Leads Biolabs (9887 HK)

Developing next-generation immuno-oncology therapies

- **Extensive pipeline across immune checkpoints, T-cell engagers and ADCs**. Leads Biolabs focuses on developing immunotherapies involving immune checkpoints, such as co-stimulatory agonists and checkpoint inhibitors, while expanding into other areas, such as CD3 T-cell engagers and ADCs. The Company has developed proprietary LeadsBody platform (CD3 T-cell engager platform) and X-body platform (4-1BB engager platform). These platforms serve as engines to drive continuous drug innovations. The X-body platform balances the affinity between TAA and 4-1BB, facilitating activation of the 4-1BB receptor only when binding to TAA at tumor sites. LBL-024 (PD-L1/4-1BB) was developed based on the X-body platform. The LeadsBody platform facilitates diverse modifications to designs of CD3 T-cell engagers, activating T-cell immunity while controlling safety risks. Among the CD3 T-cell engagers, LBL-034 (GPRC5D/CD3) is the lead asset that has demonstrated promising data.
- **LBL-024 (PD-L1/4-1BB) has the potential to become the first 4-1BB-targeted immunotherapy**. LBL-024 has entered a single-arm registrational trial in China for 3L+ EP-NEC with NDA submission expected in 3Q26, and stands as the globally first 4-1BB-targeted drug candidate to have reached registrational stage. For patients with 2L/3L+ EP-NEC, LBL-024 mono achieved ORR, mPFS and mOS of 33.3%, 2.8 months, and 11.9 months, respectively. As for 1L EP-NEC, LBL-024 (15mg/kg) + chemo delivered ORR of 83.3%, twice the ORR of recommended first-line chemotherapy. LBL-024 also demonstrated minimal liver toxicity in terms of AST and ALT level increase. The Company targets to submit the BLA by 3Q26 for EP-NEC based on the single-arm trial. The broad expression of 4-1BB and PD-L1 provides substantial opportunities for expanding the indications of LBL-024 across various tumors, particularly NECs, SCLC, NSCLC, BTC, and HCC. For 1L SCLC as observed in Ph1b/2 trial, LBL-024 in combination with chemotherapy delivered promising ORR of 86.5% (45/52). We expect further data readout of LBL-024 in 1L SCLC.
- **LBL-034 is the second most clinically advanced GPRC5D-targeted CD3 T-cell engager globally with favorable safety profile.** LBL-034 is designed to activate T cells within the GPRC5D-expressing TME, minimizing the safety concerns associated with off-target CD3 engagement. For relapsed/refractory MM, LBL-034 monotherapy delivered CR+sCR of 44.4% at 400μg/kg and 50.0% at 800μg/kg in a Ph1/2 trial, comparing to TALVEYR's 22.7% at dose of 800μg/kg. LBL-034 also induced lower levels of cytokine release than the analog of TALVEYR. Updated data of LBL-034 will be released at the 2025 ASH meeting, and a potential pivotal trial is in planning.
- **Initiate at BUY with a TP of HK$80.27**. We are positive on the Company's development of PD-L1/4-1BB and TCEs as next-generation IO. We derive our target price of HK$80.27 based on a DCF model (WACC: 9.06%, terminal growth rate 4.0%).

Earnings Summary

(YE 31 Dec)	FY23A	FY24A	FY25E	FY26E	FY27E
Revenue (RMB mn)	9	0	251	0	359
Adjusted net profit (RMB mn)	(362.2)	(301.2)	(176.0)	(414.9)	(318.7)
EPS (Reported) (RMB)	na	na	(0.88)	(2.09)	(1.60)
R&D expenses (RMB mn)	(231)	(186)	(300)	(360)	(431)
Admin expenses (RMB mn)	(38)	(88)	(150)	(100)	(126)

Source: Company data, Bloomberg, CMBIGM estimates

BUY (Initiate)

Target Price	**HK$80.27**
Up/Downside	**26.4%**
Current Price	**HK$63.50**

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Stock Data

Mkt Cap (HK$ mn)	12,629.6
Avg 3 mths t/o (HK$ mn)	191.6
52w High/Low (HK$)	NA/NA
Total Issued Shares (mn)	198.9

Source: FactSet

Shareholding Structure

Suzhou Jianxin Hankang	6.5%
Kang Xiaoqiang	5.6%

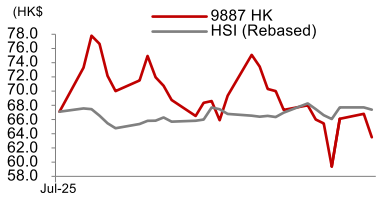
Source: Bloomberg

Share Performance

	Absolute	Relative
1-mth	-9.3%	-12.8%
3-mth	NM	NM
6-mth	NM	NM

Source: FactSet

12-mth Price Performance



Source: FactSet

Content

Investment thesis

Nanjing Leads Biolabs (Leads Biolabs) is a clinical-stage biotechnology company focused on new therapies in oncology, autoimmune, and other severe diseases, led by its PD-L1/41-BB and T-cell engager assets.

Extensive pipeline across immune checkpoints, T-cell engagers and ADCs

Leads Biolabs not only focuses on developing immunotherapies involving immune checkpoints, such as co-stimulatory agonists and checkpoint inhibitors, but also expands into other therapeutic strategies, such as CD3 T-cell engagers and ADCs. Leveraging its proprietary technology platforms and drug development capabilities, Leads Biolabs has curated a rationally designed and differentiated pipeline of 14 drug candidates, including (i) three monoclonal antibodies, four bispecific antibodies, two antibody-drug conjugates (ADCs), and a bispecific fusion protein for oncology, as well as (ii) a bispecific fusion protein and a trispecific antibody for autoimmune diseases.

Out of these 14 drug candidates, six have been successfully progressed into the clinical stage. To date, the Company has achieved proof-of-concept from Phase II clinical trials for two drug candidates, LBL-024 (PD-L1/41-BB) and LBL-034 (GPRC5D/CD3) in three indications and advanced one of these candidates into the registrational trial stage.

Multiple major immune-oncology assets among global top three most advanced candidates

LBL-024 (PD-L1/4-1BB bispecific antibody) has the potential to become the globally first 4-1BB-targeted immunotherapy with extensive indication expansion opportunities, across EP-NEC, SCLC, BTC, NSCLC and other solid tumors. LBL-024 has entered into a single-arm registrational trial for extra-pulmonary neuroendocrine carcinoma (EP-NEC) in China in July 2024 and stands as the globally first 4-1BB-targeted drug candidate to have reached registrational stage.

LBL-024 is specifically engineered with a 2:2 format, featuring two binding domains for each of PD-L1 and 4-1BB and a significantly differentiated affinity ratio of approximately 1:300 for 4-1BB versus PD-L1, enabling LBL-024 to conditionally activate 4-1BB-mediated T cell immune responses within the TME only when PD-L1 is present, while simultaneously alleviating the immune suppression by inhibiting the PD-1/L1 pathway. The conditional activation strategy localizes the 4-1BB activation to the tumor site and significantly reduces the risk of toxicities associated with systemic exposure, including liver toxicity and over-activation of 4-1BB.

For patients with 2L/3L+ EP-NEC, LBL-024 monotherapy achieved ORR, mPFS and mOS of 33.3%, 2.8 months, and 11.9 months, respectively, favorable in cross-trial comparison to Keytruda's 7%, 1.8 months, and 7.8 months for 2L/3L+ patients, and Opdivo's 7.2%, 1.8 months and 7.2 months for 2L patients. For patients with 1L EP-NEC, LBL-024 in combination with chemotherapy delivered ORR of 83.3% at the 15 mg/kg dosage, which is approximately twice the ORR of recommended first-line chemotherapy regimens (ORR typically 30-55%). In terms of liver toxicity, in monotherapy, only 1.1% (2/175) of patients experienced Grade 3 or higher adverse events related to increased AST levels, and only 0.6% (1/175) of patients showed increased ALT levels. Both AST and ALT levels are key indicators of liver toxicity. Leads Biolabs is conducting a single-arm registrational trial in China to evaluate LBL-024 monotherapy in late-line EP-NEC.

The broad expression nature of 4-1BB and PD-L1 provides opportunities for expanding the indications of LBL-024 across various solid tumors, particularly NECs, SCLC (which is also an aggressive form of NEC), NSCLC, BTC, ESCC, HCC and GC, thereby offering extensive market potential. For 1L SCLC, LBL-024 in combination with chemotherapy delivered ORR of 86.5% (45/52), presenting a strong case for its potential development as a frontline treatment for SCLC. In July 2025, first patient in the Phase II trial for LBL-024 in combination with SoC for NSCLC was enrolled. The Company also plans to commence Phase II studies of LBL-024 in combination with SoC for the treatment of BTC, HCC, melanoma and OC in 3Q25, TNBC in 2H25, and ESCC and GC in 1H26.

LBL-034 is the second most clinically advanced GPRC5D-targeted CD3 T-cell engager globally with favorable safety profile. It is designed with a 2:1 format by harnessing the Company's proprietary LeadsBody platform. The tailored positioning and spatial arrangement of the molecule enable LBL-034 to selectively bind to T cells only when GPRC5D+ cells are present, thereby conditionally activating T cells within the GPRC5D-expressing TME. This distinct molecular design and conditional T-cell activation mechanism minimize the safety concerns associated with off-target CD3 engagement and lower risks related to cytokine release syndrome (CRS). Including TALVEYR (talquetamab) by Janssen Biotech which has been approved for MM in the US, LBL-034 is the second most clinically advanced GPRC5D-targeted CD3 T-cell engager globally. In its monotherapy Phase I/II trial targeting relapsed/refractory MM, ORR of 77.8% (14/18) and CR+sCR rate of 44.4% at 400 μg/kg and CR+sCR rate of 50.0% at 800 μg/kg were observed, comparing to TALVEYR (talquetamab)'s CR+sCR rate of 22.7% in the patients with MM at a dose of 800 μg/kg. LBL-034 also induced lower levels of cytokine release than the analog of TALVEYR (talquetamab). This suggests that LBL-034 presents a reduced risk of CD3-related CRS, indicating a potentially more favorable safety profile. No DLT or Grade ≥ 3 CRS were observed up to a dosage of 800 μg/kg.

Two proprietary R&D platforms for T-cell activation

The Company has developed proprietary technology platforms, including LeadsBody platform (a CD3 T-cell engager platform), X-body platform (a 4-1BB engager platform), and several other bispecific antibody and fusion protein platforms. These technology platforms offer the Company a broad arsenal of advanced tools and techniques for designing, screening and optimizing antibodies, serving as the engine to drive continuous drug innovations for different targets, mechanisms of action, and modalities.

The X-body platform (4-1BB engager platform) applies advanced antibody engineering technology to balance the affinity between TAA and 4-1BB, facilitating the crosslinking and activation of the 4-1BB receptor only when binding to TAA at tumor sites, thereby localizing 4-1BB activation in TAA expressing tumor microenvironment. Such unique molecular structure can bolster the immune response within the tumor microenvironment, while mitigating the risk of systemic toxicities. The Company's core product LBL-024 was developed based on the X-body platform.

The LeadsBody platform (CD3 T-cell engager platform) facilitates diverse modifications to molecular designs of CD3 T-cell engagers, thereby effectively activating T-cell immunity while controlling the safety risks caused by cytokine releases. The T-cell engagers developed on this platform share a unique 2:1 asymmetrical structure, with precisely tailored positioning and spatial arrangement of their binding arms. These molecules exhibit relatively low affinity for CD3 and higher affinity for tumor-specific antigens. This differentiated design minimizes safety concerns associated with on-target off-tumor CD3 engagement and reduces T-cell apoptosis, which are common challenges in the development of T-cell engagers. With well-balanced efficacy and safety profiles, the Company's CD3 T-cell engagers can potentially achieve a greater therapeutic window and enhance the therapeutic impact across both liquid and solid tumors. Among the CD3 T-cell engagers, LBL-034 is the lead asset.

Initiate at BUY with TP of HK$80.27

We are positive on the Company's development of PD-L1/4-1BB and TCEs as next-generation IO. We derive our target price of HK$80.27 based on a DCF model (WACC: 9.06%, terminal growth rate 4.0%).

Investment risks

Risks relating to (1) research and development of drug candidates; and (2) continuing to incur net losses.

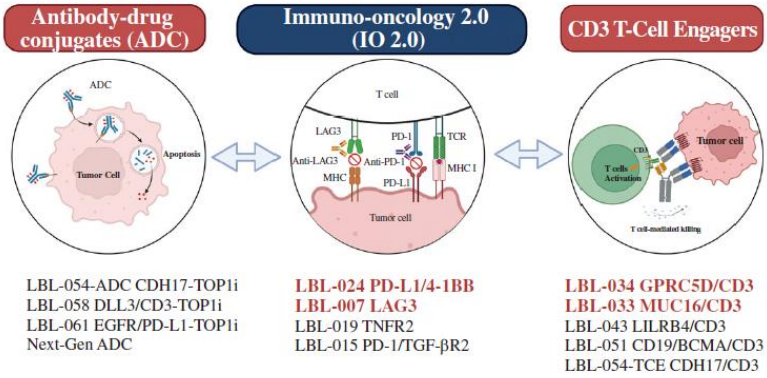
Developing next-generation immune-oncology treatment as a front-runner

Leads Biolabs is a clinical-stage biotechnology company focused on new therapies in oncology, autoimmune, and other severe diseases, led by its PD-L1/41-BB and T-cell engager assets. The Company has built a diversified portfolio with multiple assets positioned as a clinically advanced candidate on a global scale, either in its class or among those addressing the same target(s).

Extensive pipeline across immune checkpoints, T-cell engagers and ADCs

Leads Biolabs not only focuses on developing immunotherapies involving immune checkpoints, such as co-stimulatory agonists and checkpoint inhibitors, but also expands into other therapeutic strategies, such as CD3 T-cell engagers and ADCs.

Figure 1: Leads Biolabs's cancer immunotherapy with multi-target, multi-modality & new combination therapies



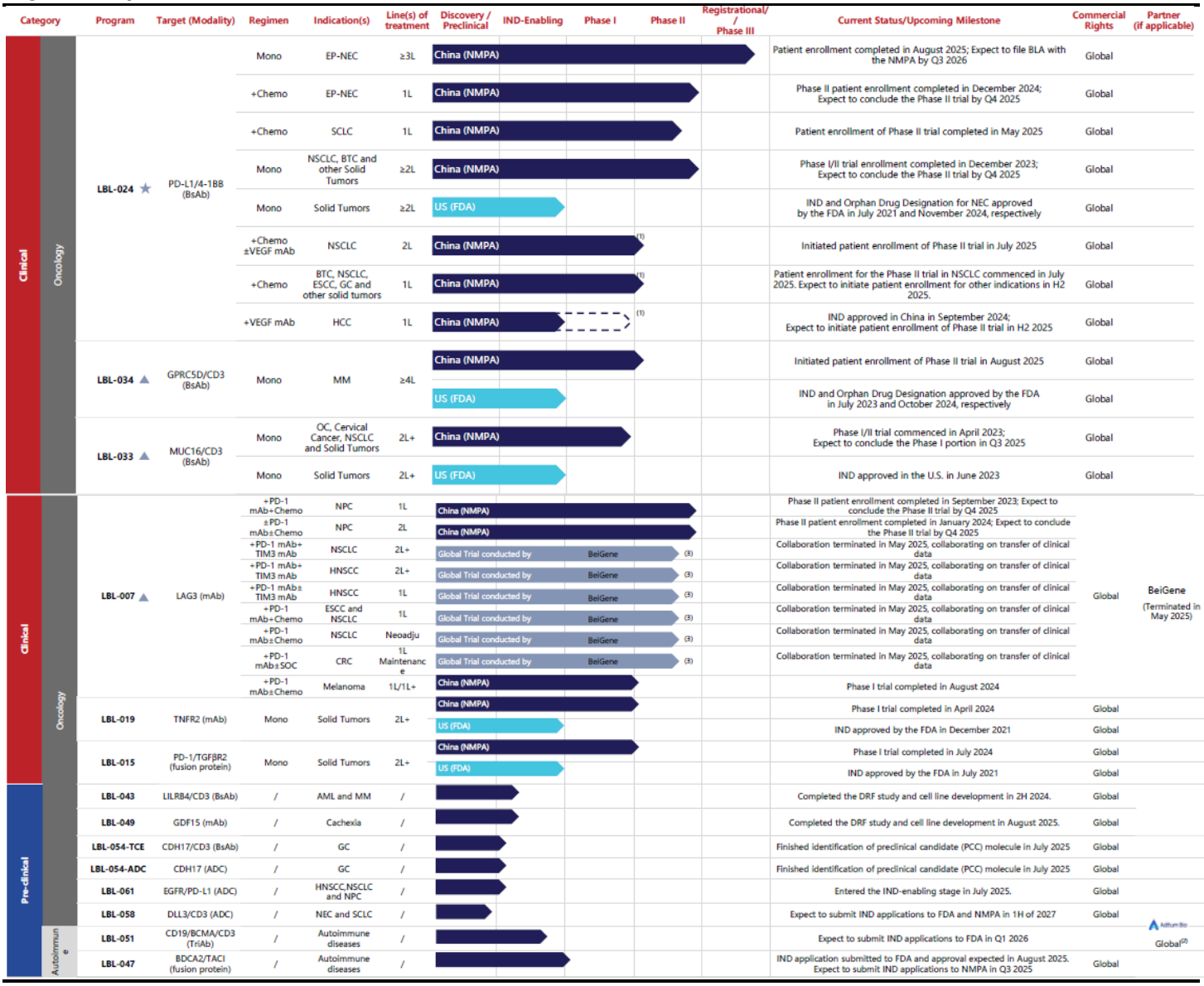
Source: Company data, CMBIGM

Leveraging its proprietary technology platforms and robust drug development capabilities, Leads Biolabs has curated a rationally designed and differentiated pipeline of 14 drug candidates, including (i) three monoclonal antibodies, four bispecific antibodies, two antibody-drug conjugates (ADCs), and a bispecific fusion protein for oncology, as well as (ii) a bispecific fusion protein and a trispecific antibody for autoimmune diseases.

Out of these 14 drug candidates, six have been successfully progressed into the clinical stage. To date, the Company has achieved proof-of-concept from Phase II clinical trials for two drug candidates, LBL-024 (PD-L1/41-BB) and LBL-034 (GPRC5D/CD3), in three indications and advanced LBL-024 into the registrational trial stage. LBL-024 has entered into a single-arm registrational trial for EP-NEC in China in July 2024 and stands as the globally first 4-1BB-targeted drug candidate to have reached the registrational stage. LBL-024 also has the potential to become the first drug approved for treating advanced EP-NEC. Additionally, the Company received the BTD in China for LBL-024 in treating late-line EP-NEC. Further, LBL-024 obtained the Orphan Drug Designation (ODD) from the FDA for the treatment of NEC in November 2024. LBL-034 is the second most clinically advanced GPRC5D-targeted CD3 T-cell engager globally.

As a testament to its drug R&D capabilities, recognizing the first-in-class potential of LBL-051 (a preclinical CD19/BCMA/CD3 T cell engager), the Company reached collaboration arrangements with a US company (NewCo) newly formed by Aditum Bio, a biotech venture firm, dedicated to the global development and commercialization of certain trispecific T cell engager, with a total deal value of up to US$614 mn plus potential mid-single-digit royalties and an equity stake in this NewCo.

Figure 2: Pipeline of Leads Biolabs



Source: Company data, CMBIGM

Major immune-oncology assets among global top three most advanced candidates

LBL-024 (PD-L1/4-1BB bispecific antibody), potentially to become the globally first 4-1BB-targeted immunotherapy with extensive indication expansion opportunities

LBL-024, the Core Product, is a PD-L1 and 4-1BB dual-targeting bispecific antibody designed to work by boosting the anti-tumor immune responses, combining the blocking of immune "brakes" with the activation of T cells. It stands as the globally first molecule targeting co-stimulatory receptor 4-1BB to have reached registrational stage, positioning the 4-1BB-based bispecific antibody as the next frontier in immune checkpoint therapy. LBL-024 has demonstrated encouraging efficacy signals and a favorable safety profile in multiple clinical trials targeting EP-NEC, small cell lung cancer (SCLC), biliary tract cancer (BTC), non-small cell lung cancer (NSCLC) and other solid tumors.

While 4-1BB has long been recognized as a promising target for immuno-oncology therapy, its clinical development has been impeded by the occurrence of severe adverse events, particularly liver toxicity due to systemic 4-1BB activation. To tackle this challenge, LBL-024 is specifically engineered with a 2:2 format, featuring two binding domains for each of PD-L1 and 4-1BB and a significantly differentiated

affinity ratio of approximately 1:300 for 4-1BB versus PD-L1. This unique molecular design enables LBL-024 to conditionally activate 4-1BB-mediated T cell immune responses within the TME only when PD-L1 is present, while simultaneously alleviating the immune suppression by inhibiting the PD-1/L1 pathway.

The conditional activation strategy localizes the 4-1BB activation to the tumor site and significantly reduces the risk of toxicities associated with systemic exposure, including liver toxicity and over-activation of 4-1BB. Additionally, LBL-024 demonstrated a broader effective concentration range (EC80) than an analog of Genmab's GEN-1046 (the other clinical-stage PD-L1/4-1BB bispecific antibody) in preclinical studies, suggesting a wider therapeutic window. Preclinical studies also revealed more potent antitumor activity of LBL-024 compared to either anti-PD-L1 antibody or anti-4-1BB antibody as a single agent. Notably, LBL-024 also exhibited strong antitumor efficacy in Keytruda resistant mouse tumor model.

LBL-024 has demonstrated encouraging efficacy signals with a favorable safety profile for the treatment of advanced EP-NEC, either as a monotherapy or in combination with chemotherapy, in clinical trials in China.

- In its monotherapy Phase I/II trial, among 45 evaluable patients with 2L/3L+ EP-NEC, 3 achieved complete response (CR), 12 achieved partial response (PR), and eight achieved stable disease (SD), indicating an objective response rate (ORR) of 33.3%, and a disease control rate (DCR) of 51.1%, as of 3 June 2025. The median progression-free survival (PFS) for the overall, 2L, and 3L+ patients was 2.8, 4.1, and 2.8 months, respectively. The median overall survival (OS) was 11.9 months, as of 3 June 2025. The 6-month OS rates for the overall, 2L, and 3L+ populations were 77.8%, 85.9%, and 70.8%, respectively. As of 3 June 2025, no dose-limiting toxicity (DLT) was observed, and the maximum tolerated dose (MTD) was not reached, even at the highest dose tested of 25.0 mg/kg. Most adverse events are Grade 1 or 2 and manageable.
- In the 1L EP-NEC cohort of the Phase Ib/II clinical trial of LBL-024 in combination with chemotherapy, the preliminary data cut off on 5 June 2025 showed that, among 52 evaluable EP-NEC patients, 3 achieved CR and 36 achieved PR, demonstrating an encouraging ORR of 75.0% (39/52). Notably, the 15mg/kg dose group showed a particularly promising ORR of 79.2% (19/24). Furthermore, during the dose optimization stage of the Phase II trial, an ORR of 83.3% was observed at the 15 mg/kg dosage, which is approximately twice the ORR of recommended first-line chemotherapy regimens (ORR typically 30-55%), as reported in publicly available clinical data. No DLTs were observed and the MTD was not reached up to 15 mg/kg.
- In terms of liver toxicity, in the monotherapy Phase I/II trial, in 175 cancer patients treated across seven dose levels from 0.2 mg/kg to 25 mg/kg once every three weeks, no DLT was observed, and the MTD was not reached, even at the highest dose tested of 25.0 mg/kg, as of 12 February 2025. Most adverse events are Grade 1 or 2 and manageable. Only 1.1% (2/175) of patients experienced Grade 3 or higher adverse events related to increased AST levels, and only 0.6% (1/175) of patients showed increased ALT levels. Both AST and ALT levels are key indicators of liver toxicity. In comparison, according to the publicly reported clinical data of Genmab's GEN-1046/acasunlimab in combination with Keytruda for the treatment of metastatic NSCLC, 8.7% of patients experienced Grade 3 or above liver-related adverse events.

In comparison, in patients with 2L/3L+ EP-NEC, the ORR, median PFS and median overall survival (mOS) of Keytruda were approximately 7%, 1.8 months, and 7.8 months, respectively. The ORR, median PFS and mOS of Opdivo were approximately 7.2%, 1.8 months and 7.2 months, respectively, in patients with 2L EP-NEC. The mOS of FOLFIRI, nivolumab as well as the combination of nivolumab and ipilimumab regimen was 8.9, 7.2 and 5.8 months, respectively, in the second-line or above treatment of EP-NEC. None of the PD-L1 inhibitors have been approved for treating EP-NEC given their limited efficacy for this indication observed in clinical trials, according to Frost & Sullivan. By comparison, meaningful insight may be drawn that LBL-024 could potentially offer a compelling treatment option for EP-NEC. LBL-024 has the potential to become the first drug approved for treating advanced EP-NEC.

In 2024, there was 17.2 thousand patients with EP-NEC in China, which is expected to increase to 23.1 thousand by 2030, according to Frost & Sullivan. In the deficient of a standard of care for EP-NEC, Leads Biolabs obtained an approval from the NMPA for a single-arm registrational trial to evaluate LBL-024 monotherapy in patients with EP-NEC who failed previous chemotherapy in April 2024, and enrolled

the first patient in this trial in July 2024. Subject to the clinical progress, the Company expects to submit a biologics license application (BLA) to the NMPA by the third quarter of 2026.

Leads Biolabs launched a Phase Ib/II study of LBL-024 in combination with etoposide and platinum-based chemotherapy in 1L EP-NEC in China in January 2024, and has completed the Phase Ib portion of this study in May 2024. The Company expects to read out the ORR and 6-month PFS/OS rates for the Phase II portion in 2026. Additionally, the Company intends to initiate a Phase III confirmatory study to provide data support for the full approval of LBL-024 specific for EP-NEC.

Beyond EP-NEC, the Company sees indication expansion opportunities with LBL-024, considering the selective expression of 4-1BB on tumor-experienced cytotoxic T cells, its key co-stimulatory effects, and the broad expression of PD-L1 across various cancer types. LBL-024's proven preliminary efficacy in advanced EP-NEC presents a strong case for its potential development for other NEC types, such as SCLC, and potentially as a frontline treatment. In the Phase Ib/II trial of LBL-024 in combination with chemotherapy, among 52 evaluable 1L SCLC patients, ORR of 86.5% (45/52) was observed in the SCLC cohort, as of 5 June 2025.

Beyond EP-NEC and SCLC, LBL-024 monotherapy has also generated preliminary efficacy signals in multiple other large cancer indications, particularly BTC and NSCLC. In July 2025, first patient in the Phase II trial for LBL-024 in combination with SoC for NSCLC was enrolled. The Company also plans to commence Phase II studies of LBL-024 in combination with SoC for the treatment of BTC, HCC, melanoma and OC in 3Q25, TNBC in 2H25, and ESCC and GC in 1H26.

LBL-034, the second most advanced GPRC5D-targeted CD3 T-cell engager globally with favorable safety profile

LBL-034, one of the key products, is a humanized bispecific T-cell engager targeting both GPRC5D and CD3. This enables to redirect T cells to selectively attack cancer cells, offering a promising therapeutic approach for the treatment of hematological malignancies. LBL-034 is one of the lead assets among the portfolio of CD3 T-cell engagers. The Company is currently evaluating the therapeutic potential of LBL-034 in a Phase I/II trial for the treatment of relapsed/refractory multiple myeloma (MM) in China. Including TALVEYR (talquetamab) by Janssen Biotech which has been approved for MM in the US, LBL-034 is the second most clinically advanced GPRC5D-targeted CD3 T-cell engager globally. Further, LBL-034 obtained the ODD from the FDA for the treatment of MM.

By harnessing the Company's proprietary LeadsBody platform, a CD3 T-cell engager platform developed in-house, LBL-034 is designed with a 2:1 format, with two high-affinity Fabs targeting GPRC5D and one scFv targeting CD3. The tailored positioning and spatial arrangement of the molecule enable LBL-034 to selectively bind to T cells only when GPRC5D+ cells are present, thereby conditionally activating T cells within the GPRC5D-expressing TME. This distinct molecular design and conditional T-cell activation mechanism minimize the safety concerns associated with off-target CD3 engagement and lower risks related to cytokine release syndrome (CRS).

LBL-034 has exhibited promising efficacy signals in preclinical studies, at a level comparable to or exceeding its major competitors. Additionally,

In its monotherapy Phase I/II trial targeting relapsed/refractory MM, ORR of 77.8% (14/18) and CR+sCR rate of 44.4% at 400 μg/kg and CR+sCR rate of 50.0% at 800 μg/kg were observed, comparing to TALVEYR (talquetamab)'s CR+sCR rate of 22.7% in the patients with MM at a dose of 800 μg/kg. LBL-034 also induced lower levels of cytokine release than the analog of TALVEYR (talquetamab). This suggests that LBL-034 presents a reduced risk of CD3-related CRS, indicating a potentially more favorable safety profile. No DLT or Grade ≥ 3 CRS were observed up to a dosage of 800 μg/kg.

According to the forecast of Janssen Biotech, TALVEYR (talquetamab) is expected to generate peak annual sales of US$5 bn worldwide in the future. In consideration of the sizable population of patients with MM, the relatively long progression-free survival of patients treated with TALVEYR, and various shortcomings of existing antibody drugs targeting other therapeutic targets, such as CD38 and BCMA, LBL-034 holds significant market potential. Based on the results from its monotherapy Phase I/II trial,

the Company plans to discuss with CDE regarding the initiation of a single-arm registrational trial in 2H25, which may allow the Company to pursue accelerated marketing approval of LBL-034 for the 4L+ treatment of MM. The Company aims to complete the single-arm registrational trial and submit the first BLA by 2H26.

LBL-007 (LAG3 monoclonal antibody)

LBL-007 is a fully human IgG4 monoclonal antibody targeting LAG3 to restore immune function, boosting T-cell activity and enhancing the effectiveness of cancer immunotherapy. It ranks among the top three LAG3-targeted clinical-stage monoclonal antibodies globally in terms of clinical development (other than the only one marketed LAG3-targeted drug), and is the first in its class with proven efficacy in NPC.

LAG3 is an immune checkpoint receptor that negatively regulates T-cell function. Configured to target unique epitopes of LAG3, LBL-007 can bind to LAG3 with high affinity and block LAG3's engagement with all four identified immune inhibitory ligands, including MHC-II, LSECtin, Gal-3 and FGL-1. Upon binding to LAG3, LBL-007 induces potent endocytosis, reducing LAG3 expression on the cell surface, which further blocks ligand interaction and enhances immune responses.

The combination therapy integrating LBL-007 and PD-1 inhibitors demonstrates promising synergistic antitumor effects and favorable safety across various tumor types in the clinical studies. Notably, in Phase II trial, LBL-007 in combination with tislelizumab (anti-PD-1 antibody) and chemotherapy achieved an ORR of 83.3% among 42 evaluable patients with 1L NPC, as of 13 January 2025. The observed 9-month PFS rate stood at 75.1% with mPFS of 15.0 months. In comparison, the ORR and median PFS of the combination of tislelizumab and chemotherapy regimen was about 69.5% and 9.2 months, respectively, in patients with recurrent/metastatic NPC, according to the publicly reported clinical data from Rationale-309 (a Phase III clinical trial for tislelizumab combined with gemcitabine and cisplatin in 1L RM-NPC). These impressive response rate and survival benefits position LBL-007 as the first LAG3 antibody to show robust efficacy in NPC.

Leads Biolabs entered into a license and collaboration agreement with BeOne Medicine in December 2021 for an exclusive license to develop, manufacture and commercialize LBL-007 outside Greater China. BeOne had then been conducting various global trials to evaluate LBL-007 in combination with tislelizumab and standard of care in NSCLC, CRC, HNSCC and ESCC. The BeOne Agreement was later terminated on 18 May 2025. Leads Biolabs remains committed to its ongoing clinical programs of LBL-007 for the treatment of advanced NPC. The Company has completed patient enrollment for the Phase Ib/II clinical trial for its combination with tislelizumab and/or chemotherapy in advanced NPC and other solid tumors in China in January 2024, and expects to complete it in the third quarter of 2025. The Company also plans to further investigate the therapeutic potential of LBL-007 in melanoma, building on clinical data from Phase I trial targeting this indication.

Two proprietary R&D platforms for T-cell activation

Through over a decade of R&D efforts, the Company has developed proprietary technology platforms, including LeadsBody platform (a CD3 T-cell engager platform), X-body platform (a 4-1BB engager platform), and several other bispecific antibody and fusion protein platforms. These technology platforms offer the Company a broad arsenal of advanced tools and techniques for designing, screening and optimizing antibodies, serving as the engine to drive continuous drug innovations for different targets, mechanisms of action, and modalities.

X-body platform (4-1BB engager platform):

The X-body platform applies advanced antibody engineering technology to balance the affinity between TAA and 4-1BB, facilitating the crosslinking and activation of the 4-1BB receptor only when binding to TAA at tumor sites, thereby localizing 4-1BB activation in TAA expressing tumor microenvironment. Such unique molecular structure is able to bolster the immune response within the tumor microenvironment, while mitigating the risk of systemic toxicities. The Company's core product LBL-024 was developed based on the X-body platform.

4-1BB/PD-L1 bispecific antibody presents a next-generation immuno-oncology therapeutic approach in countering cancer's immune evasion mechanisms by simultaneously enhancing T-cell responses and restoring tumor immunosurveillance, which offers potential benefits to patients who do not respond to existing immunotherapies or have experienced a relapse. The broad expression nature of 4-1BB and PD-L1 offers significant indication expansion opportunities for LBL-024 across a range of solid tumors.

LeadsBody platform (CD3 T-cell engager platform):

CD3 T-cell engagers may lead to strong antitumor responses in a wide range of cancers, including those that are insensitive or have relapsed after the treatment of immune checkpoint inhibitors. CD3 T-cell engagers have demonstrated considerable therapeutic promise across various hematological malignancies, and are increasingly proving efficacious in solid tumors as well. Their potential to synergize with other cancer treatments, such as chemotherapy and other immunotherapies, may further expand their application across numerous cancer types. This versatility and effectiveness position CD3 T-cell engagers as a promising approach at the frontier of the development of next-generation immunotherapies.

Leveraging its extensive expertise in bispecific antibody engineering, the Company has established the proprietary LeadsBody platform to facilitate diverse modifications to molecular designs of CD3 T-cell engagers, thereby effectively activating T-cell immunity while controlling the safety risks caused by cytokine releases. The T-cell engagers developed on this platform share a unique 2:1 asymmetrical structure, with precisely tailored positioning and spatial arrangement of their binding arms. These molecules exhibit relatively low affinity for CD3 and higher affinity for tumor-specific antigens, aligning with the understanding that the affinity balance correlates with target-dependent killing activity by T-cell engagers. This differentiated design minimizes safety concerns associated with on-target off-tumor CD3 engagement and reduces T-cell apoptosis, which are common challenges in the development of T-cell engagers. With well-balanced efficacy and safety profiles, the Company's CD3 T-cell engagers can potentially achieve a greater therapeutic window, extend the duration of treatment, enhance the therapeutic impact across both liquid and solid tumors, and ultimately improve patients' quality of life.

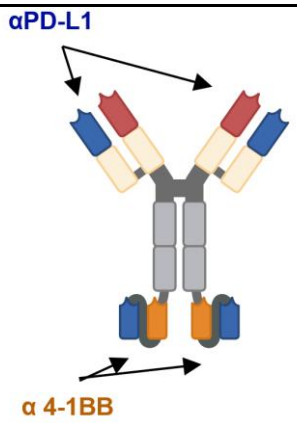
The LeadsBody platform possesses these significant advantages: 1) optimized proportions and affinities of TAA and CD3 binding domains directing the action of T-cell engagers to the tumor site, minimizing off-target toxicity; 2) structural optimizations inducing effective killing of target cells by T cells while reducing cytokine secretion; 3) both *in vitro* and *in vivo* studies, T-cell engagers exhibited durable antitumor effects with less T-cell exhaustion induction.

Among the CD3 T-cell engagers, LBL-034 is the lead asset that has demonstrated encouraging outcomes in preclinical studies and early-stage clinical trials, validating the excellence of the LeadsBody platform in the development of potent CD3 T-cell engagers.

LBL-024 (PD-L1/4-1BB), potentially the globally first molecule targeting co-stimulatory receptor 4-1BB with extensive indication expansion opportunities

LBL-024 is a tetravalent bispecific antibody that simultaneously targets PD-L1 and 4-1BB, serving dual functions: blocking the immunosuppressive PD-1/PD-L1 pathway, and selectively co-stimulating 4-1BB in the tumor microenvironment to enhance immune responses. It is being developed for the treatment of extra-pulmonary neuroendocrine carcinoma (EP-NEC), small cell lung cancer (SCLC), biliary tract cancer (BTC), non-small cell lung cancer (NSCLC) and other solid tumors. The company plans to further investigate its therapeutic potential in other untapped or underserved cancer indications, such as esophageal squamous cell carcinoma (ESCC), gastric cancer (GC) and hepatocellular carcinoma (HCC). LBL-024 stands as the globally first 4-1BB targeted molecule to have reached pivotal stage, positioning 4-1BB as the next druggable immune checkpoint following PD-1/PD-L1, CTLA-4 and LAG3. It has also exhibited the potential to become the first drug approved for treating EP-NEC. Further, the Company has received the BTD for LBL-024 in treating late-line EP-NEC from the NMPA in October 2024, as well as the ODD in treating NEC from the FDA in November 2024.

Figure 3: The molecular structure of LBL-024



Source: Company data, CMBIGM

LBL-024 is a bispecific antibody designed to simultaneously target both 4-1BB and PD-L1. As illustrated above, LBL-024's structure comprises an IgG (shown in blue and red) connected to two single chain fragment variables (scFv) (shown in blue and brown) positioned at the C-terminal end of the IgG's Fc part. The two Fabs of IgG portion target PD-L1, while the two scFvs target 4-1BB. The binding affinity of LBL-024 for PD-L1 versus 4-1BB is approximately 300:1, indicating a much stronger interaction with PD-L1 compared to 4-1BB.

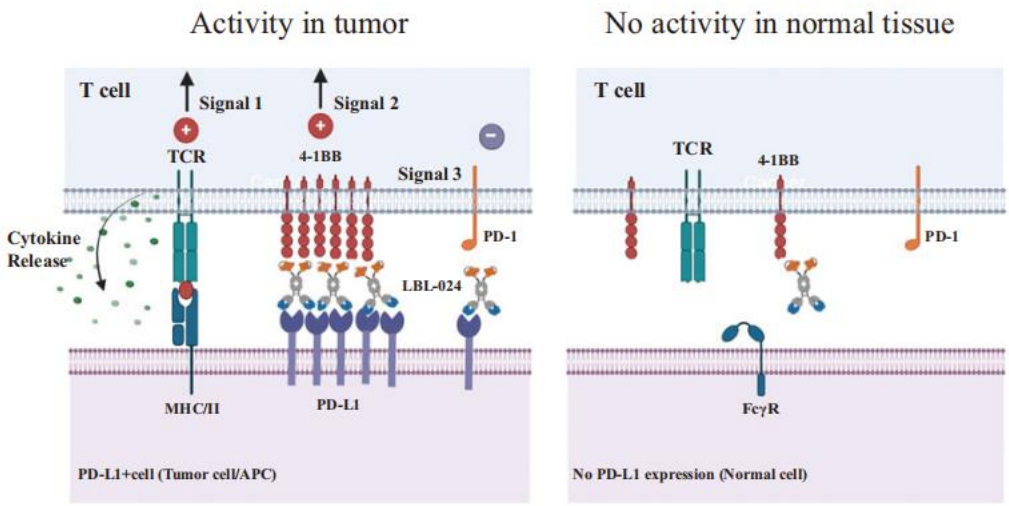
4-1BB is an inducible costimulatory receptor expressed on activated T cells and NK cells, playing a crucial role in regulating various signaling pathways to generate T-cell immune responses. PD-L1, a ligand of PD-1, is mainly expressed on tumor cells, and a key checkpoint inhibitor implicated in tumor immune evasion.

LBL-024 targets PD-L1 with high affinity, effectively blocking the PD-L1/PD-1 immunosuppressive pathway and activating T cells. It activates T-cell specific responses by restoring the engagement of T cell receptors (TCR) with MHC molecules on tumor cells or antigen-presenting cells (APCs). Upon binding to PD-L1 on tumor cells or APCs, LBL-024 simultaneously engages the 4-1BB receptor on T cells, further enhancing T-cell activation and the immune response against tumors. This interaction facilitates the cross-linking of PD-L1 expressing tumor cell membranes with 4-1BB expressing lymphocytes to conditionally activate 4-1BB signaling, which intensifies T-cell activation, growth, and antitumor responses.

By specifically binding to PD-L1, a tumor-associated antigen, LBL-024 localizes its co-stimulation of 4-1BB within the tumor environment. Different from PD-1/PD-L1 monoclonal antibodies, LBL-024 can activate the 4-1BB signaling pathway in such a localized and conditional method. The activation of 4-

1BB receptor by LBL-024 is in a PD-L1 binding-dependent manner, as demonstrated in the Company's in vitro studies. Compared to other 4-1BB/PD-L1 bispecific antibodies in global pipeline, this targeted approach, together with the fine-tuned low affinity for 4-1BB, minimizes LBL-024's interaction with 4-1BB elsewhere in the body, such as in the peripheral blood, thereby reducing the risks of systemic organ toxicity, including liver damage, as demonstrated in the following figure. The difference of LBL-024's affinity between the 4-1BB and PD-L1 does not affect its anti-tumor effects in the tumor environment. Leads Biolabs' preclinical studies showed that, LBL-024 is able to robustly activate the 4-1BB signaling pathway in the presence of PD-L1 positive cells. In addition, such binding affinity difference allows for a broader effective concentration range as revealed in the preclinical studies as well, as compared to other competitors.

Figure 4: Mechanism of action of LBL-024



Source: Company data, CMBIGM

Broad market opportunities across various tumor types, including NECs, SCLC, NSCLC, BTC, and so on

Bispecific antibodies targeting both PD-L1 and 4-1BB constitutes a promising therapeutic approach in cancer treatments. These two key pathways have independent and complementary immunosuppressive functions, with partially non-redundant effects on the immune systems. 4-1BB can enhance T cell proliferation and survival when activated, while PD-1 inhibitors alleviate immune suppression by disrupting PD-1 interactions. The inhibition of PD-L1 and activation of 4-1BB through a bispecific antibody can enhance antitumor activity. Notably, targeting both PD-L1 and 4-1BB within the TME is considered more critical than inhibiting these targets in peripheral blood. 4-1BB impacts tumor cell-extrinsic processes that modify the local microenvironment. This approach is especially important for immune-excluded and immune-desert tumors, where the local immune suppression is more pronounced. By focusing on the TME, the therapeutic strategy can more effectively overcome the local barriers to immune cell infiltration and activation, thereby enhancing the overall antitumor response.

Even though 4-1BB has been acknowledged as a promising target for immuno-oncology therapy, clinical development of 4-1BB-targeted candidates has been impeded by the occurrence of severe adverse events, particularly liver toxicity due to systemic 4-1BB activation. For example, clinical investigations of urelumab (4-1BB mAb) were terminated due to severe liver toxicity, and clinical investigations of utomilumab (4-1BB mAb) were terminated due to low efficacy. Leads Biolabs' LBL-024, leveraging its 2:2 format with significantly differentiated affinity for 4-1BB and PD-L1, demonstrated superior safety in the Phase I/II clinical trials. With its unprecedented efficacy profile, LBL-024 has achieved a rapid clinical progress among the PD-L1/4-1BB bispecific candidates globally, being the world's first and only 4-1BB-targeted immunotherapy to have reached the registrational trial stage.

LBL-024 stands as the globally first molecule targeting co-stimulatory receptor 4-1BB to have reached the pivotal stage with no marketed 4-1BB or PD-L1/4-1BB products.

Figure 5: Clinical-stage PD-L1/4-1BB bispecific antibodies globally

Drug Name	Target	Company	Clinical Stage	Indication	Mono or Combo Therapy in Trial Design	First Posted Date
LBL-024	PD-L1/4-1BB	Leads Biolabs Co., Ltd.	Registrational stage*	Advanced EP-NEC	Mono	2024-07-11
			Phase 2	Advanced Solid Tumor	Combo	2025-01-21
Acasunlimab	PD-L1/4-1BB	Genmab	Phase 3	NSCLC	Combo	2024-10-10
INBRX-105	PD-L1/4-1BB	Inhibrx Biosciences, Inc	Phase 2	NSCLC, Melanoma, HNSCC, GC, RCC, Esophageal Adenocarcinoma, NPC, Oropharyngeal Cancer	Mono	2019-01-18
QLF31907	PD-L1/4-1BB	Qilu Pharmaceutical CO., LTD.	Phase 2	Melanoma, UC	Mono	2023-04-21
AP203	PD-L1/4-1BB	AP Biosciences Inc.	Phase 1/2	NSCLC, HNSCC, ESCC and Other Solid Tumor	Mono	2022-07-25
PM1003	PD-L1/4-1BB	Biotheus Inc.	Phase 1/2	Advanced Solid Tumor	Mono	2023-05-17
MCLA-145	PD-L1/4-1BB	Merus N.V./Incyte Corporation	Phase 1	Advanced Solid Tumor, B-cell Lymphoma	Mono	2019-04-19
FS222	PD-L1/4-1BB	invoX Pharma Limited/F-star Therapeutics Limited	Phase 1	Advanced Solid Tumor	Mono	2021-02-05
ABL503	PD-L1/4-1BB	ABL Bio, Inc.	Phase 1	Advanced Solid Tumor	Mono	2021-02-21
ATG-101	PD-L1/4-1BB	Antengene Biologics Limited	Phase 1	Advanced Solid Tumor, B-cell NHL	Mono	2021-08-03
BH3120	PD-L1/4-1BB	Hanmi Pharmaceutical Company Limited	Phase 1	Advanced Solid Tumor	Mono	2024-01-31

Source: ClinicalTrials.gov, Frost & Sullivan Analysis, Company data, CMBIGM.
Note: Industry information as of 28 May 2025. LBL-024 was approved in April 2024 to initiate a registrational study.

The broad expression nature of 4-1BB and PD-L1 provides substantial opportunities for expanding the indications of LBL-024 across various solid tumors, particularly NECs, SCLC (which is also an aggressive form of NEC), NSCLC, BTC, ESCC, HCC and GC, thereby offering extensive market potential.

NEC: Currently, no drugs have been approved for this specific condition. Leads Biolabs' LBL-024 has entered into a single-arm pivotal trial for EP-NEC in China in July 2024, and stands as the globally first 4-1BB-targeted drug candidates to have reached registrational stage. Additionally, in its monotherapy Phase I/II trial targeting 2L/3L+ EP-NEC, the mOS reached 11.9 months. In comparison, the mOS of FOLFIRI, nivolumab as well as the combination of nivolumab and ipilimumab regimen was 8.9, 7.2 and 5.8 months, respectively, in the second-line or above EP-NEC, according to their respective publicly reported clinical data. Based on such encouraging trial results and as the most clinically advanced candidate in its class, LBL-024 has the potential to become the first drug approved for treating EP-NEC, which should afford the Company with improved negotiation ability on drug price upon commercialization. Platinum-based combination chemotherapy remains the first-line SOC for advanced NEC. The treatment options after the first-line treatment are very limited.

SCLC: In recent years, combining PD-1/PD-L1 inhibitors with chemotherapy has been recommended for treating extensive-stage SCLC in both first and later-line settings. However, the benefits of this combination therapy have been disappointing. Most patients either have primary resistance or quickly develop acquired resistance to current treatments, and very few drugs are approved for effective second-line treatment of SCLC. Without effective treatment options, the prognosis for SCLC patients is poor, with a median overall survival (mOS) of 15 to 20 months for limited-stage disease, 8 to 13 months for extensive-stage disease and 4 to 5 months for relapsed or refractory disease. Targeting 4-1BB and PD-L1 offers a promising strategy to overcome SCLC treatment limitations. This dual-target approach aims to sustain and amplify the antitumor response, reduce resistance, and improve treatment efficacy, offering new solutions for patients with extensive-stage SCLC.

NSCLC: Most patients with NSCLC are diagnosed at an advanced or metastatic stage. Immunotherapy, such as PD-1/PD-L1 inhibitors, either alone or in combination with chemotherapy, is currently at the

forefront of treatment for oncogenic driver-negative NSCLC. However, its current application is limited to a subset of patients who respond positively to ICIs and show limited effectiveness, leaving significant unmet medical needs within this large patient group. Therapies that adopt a dual-targeting approach may enhance treatment outcomes and provide substantial clinical benefits for NSCLC patients who have limited responses to PD-1/PD-L1 inhibitors.

BTC: Currently, the treatment options for BTC are limited, with a majority of patients presenting with locally advanced or metastatic disease. While monospecific antibodies targeting PD-L1 have demonstrated durable clinical benefits and long-term remissions, their effectiveness is confined to a small subset of patients who respond positively to PD-L1 inhibitors. Recent advancements suggest that bispecific antibodies, such as PD-L1/4-1BB, which can simultaneously bind to both co-inhibitory and co-stimulatory molecules, may enhance durable antitumor responses.

HCC: According to Frost & Sullivan, around 70.0% of advanced HCC patients receive the first-line treatment. Due to the limited improvement in clinical outcomes with small molecule targeted drugs, PD-1/PD-L1 inhibitors have been introduced to improve outcomes. Despite this, current immuno-oncology therapies still do not provide significant benefits in terms of progression-free and overall survival. The limited efficacy of these treatments highlights the urgent need for more effective strategies, such as bispecific antibodies.

ESCC: The efficacy of current treatments for advanced ESCC remains limited. Firstly, these PD-1/PD-L1 inhibitor-based therapies offer limited benefits due to a relatively low response rate in advanced ESCC patients, and the modest improvement in OS, typically around 3 to 6 months. Additionally, many patients develop resistance after the initial treatment, leading to reduced efficacy.

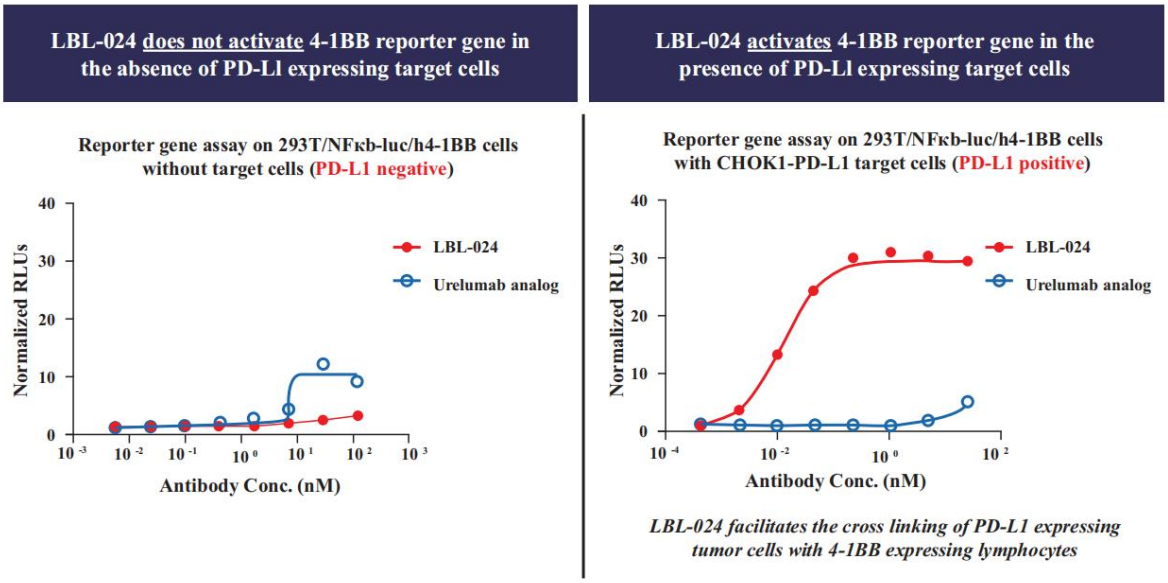
GC: Surgery is the preferred treatment for resectable GC, aiming to completely remove cancerous lesions. For HER2-positive GC, trastuzumab combined with chemotherapy is the standard first-line treatment. PD-1 inhibitors are also recommended for advanced cases. However, the high heterogeneity of GC results in varied responses to immunotherapy, with about 20% of patients achieving an active response, according to Frost & Sullivan. Despite these treatments, there remains an urgent need for more effective strategies to improve patient outcomes.

Strong competitive advantages as potentially the first marketed 4-1BB-targeted agent

Localized and conditional activation of 4-1BB that leads to minimized liver toxicity and a wide therapeutic window

The development of 4-1BB agonists is challenged by the major obstacle of dose-limiting liver toxicity. To address this issue, the Company has engineered a unique bispecific antibody, LBL-024, in a 2:2 format, with an affinity ratio of 300:1 for PD-L1 versus 4-1BB. This dual-targeting strategy enhances the specificity of 4-1BB activation by confining the co-stimulation and subsequent immune activation to the PD-L1 expressing tumor environment. The precisely designed affinity ratio between 4-1BB and PD-L1 ensures that the therapeutic effect remains potent and synergistic, characteristic of dual-functional therapies, while significantly reducing systemic toxicity. This is achieved by avoiding on-target off-tumor stimulation of 4-1BB in peripheral tissues outside the tumor. Consequently, LBL-024 demonstrates a markedly improved safety profile, offering a broad therapeutic window for effective cancer treatment.

Figure 6: Selected safety data of LBL-024

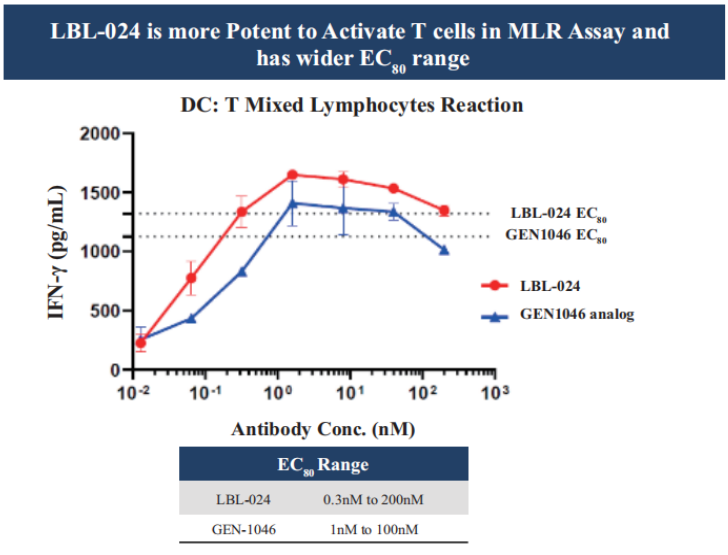


Source: Company data, CMBIGM

Results from preclinical studies of LBL-024 reflected the aims of Leads Biolabs' design and demonstrated its advantages as compared to anti-4-1BB monoclonal antibodies and other 4-1BB/PD-L1 bispecific antibodies. As illustrated in the figure above, LBL-024 conditionally activates 4-1BB in a PD-L1 binding-dependent manner in vitro, showing minimal activation of the 4-1BB receptor in the absence of PD-L1 expressing target cells, unlike the monoclonal antibody urelumab. However, in the presence of PD-L1 positive cells, LBL-024 robustly activates the 4-1BB signaling pathway.

Additionally, LBL-024 exhibits a significantly higher binding affinity for PD-L1 versus 4-1BB, with a ratio of 300:1, compared to other PD-L1/4-1BB bispecific antibodies like GEN1046 (PD-L1/4-1BB), which has an affinity ratio of 0.9:1. This unique design allows LBL-024 to demonstrate a broader effective concentration range (EC80) in preclinical assays, indicating a wider therapeutic window compared to GEN1046, as shown in the figure below.

Figure 7: A broader effective concentration range (EC80) in preclinical assays



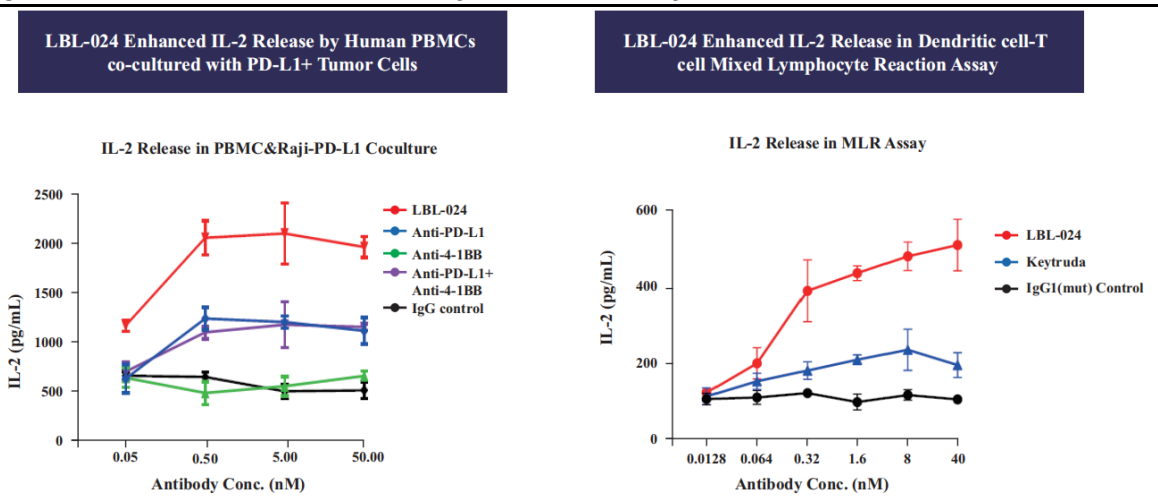
Source: Company data, CMBIGM

In both clinical trial and preclinical animal studies, the Company observed favorable safety profile and a broad therapeutic window for LBL-024. In toxicology study in cynomolgus monkeys, repeated dosing of LBL-024 (20-200 mg/kg) was well tolerated. HNSTD in cynomolgus monkeys was confirmed at 200 mg/kg, and no liver toxicity was observed. In the completed Phase I/II trial, 175 patients (111 patients in Phase II) were treated across a broad dose level from 0.2 mg/kg – 25 mg/kg Q3W. No DLT was observed and was not reached even at the highest does tested of 25 mg/kg. Most adverse events are Grade 1 or 2 and manageable. Out of 175 patients, only 1.1 (2/175) and 0.6% (1/175) patients experienced ≥3 grade adverse events of increases in AST and ALT levels, respectively, both of which are key indicators of liver toxicity. The most frequently reported treatment-emergent adverse events (≥20%) included anemia (34.3%), increased AST levels (32.6%), increased ALT levels (27.4%), leukopenia (20.0%).

Synergistic antitumor efficacy through dual-targeting strategy

LBL-024 demonstrates a unique structural composition characterized by a dual-targeting approach and a 2:2 format. The dual-targeting approach and 2:2 format of LBL-024 are instrumental in driving its superior antitumor efficacy and cytokine release observed in both in vitro and in vivo studies. This design enables LBL-024 to concurrently engage multiple molecular targets, thereby enhancing its specificity and potency against cancer cells. Moreover, the precise molecular arrangement optimizes binding affinity, further bolstering its therapeutic effectiveness. As shown in the figures below, in in vitro and in vivo studies, LBL-024 exhibited more potent antitumor activity and cytokine release compared to anti-PD-1 antibodies and anti-4-1BB antibodies, either alone or in combination. Notably, LBL-024 induced increased cytokine release, particularly interleukin-2 (IL-2), highlighting its potential as a potent therapeutic agent in oncology.

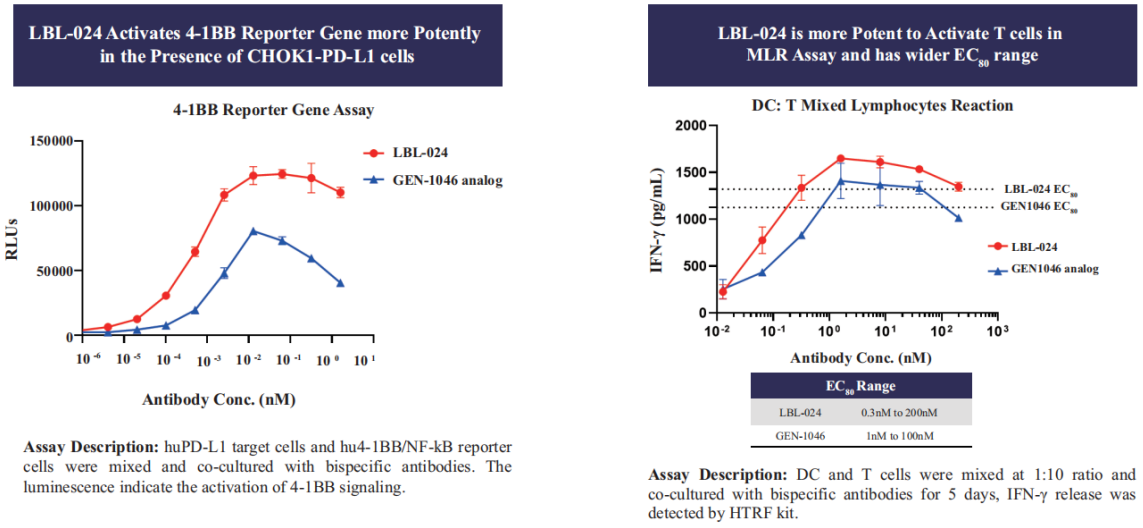
Figure 8: Selected data of enhanced cytokine release by LBL-024



Source: Company data, CMBIGM

As demonstrated by the figures below, in both the reporter gene assay and the mixed lymphocyte reaction (MLR) assay, LBL-024 exhibited heightened efficacy in activating 4-1BB signaling and stimulating IL-2 release compared to GEN-1046.

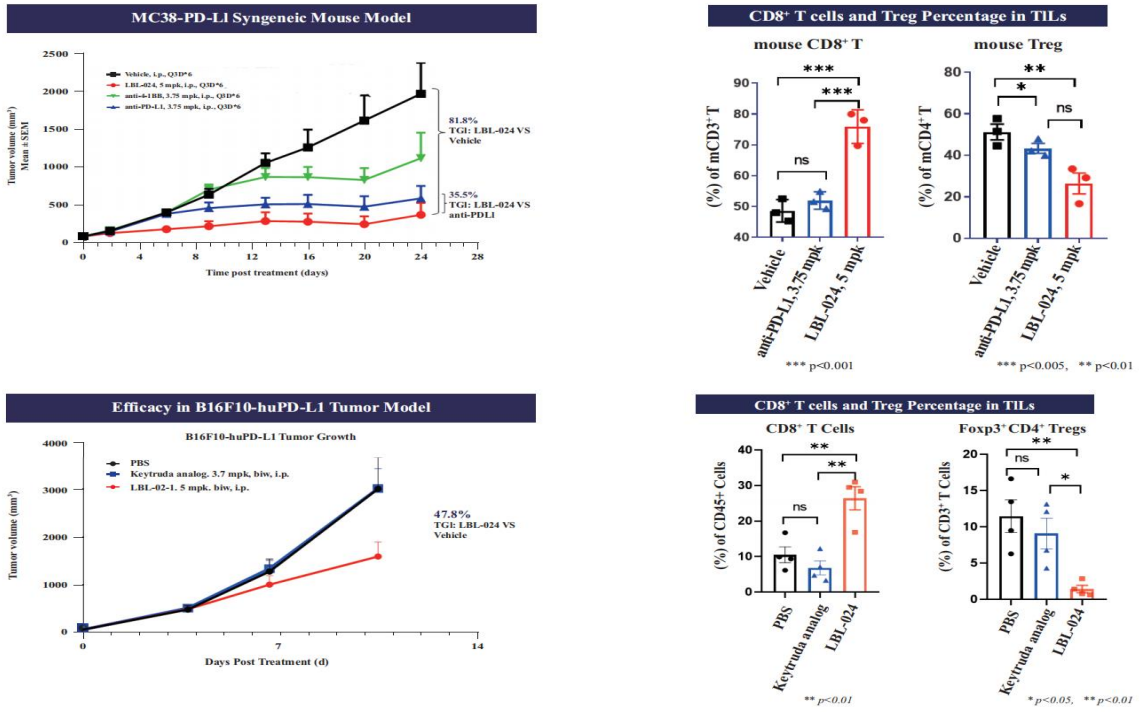
Figure 9: Comparative efficacy of LBL-024 and GEN-1046 in 4-1BB signaling and IL-2 release



Source: Company data, CMBIGM

Moreover, LBL-024 demonstrated superior antitumor efficacy in both PD-1/L1 sensitive and resistant mouse models, resulting in substantial infiltration of CD8+ T cells into the tumor microenvironment. These findings underscore the robust potential of LBL-024 as a promising candidate for further investigation and development in immunotherapy strategies targeting cancer.

Figure 10: Superior antitumor efficacy in both PD-1/L1 sensitive and resistant mouse models



Source: Company data, CMBIGM

Furthermore, LBL-024 demonstrated robust efficacy in treating patients with EP-NEC. As of 3 June 2025, out of the 45 evaluable patients with 2L/3L+ EP-NEC and measurable lesions, 3 achieved CR and 12 achieved PR. The ORR was 33.3%, surpassing both the SOC and currently available immunotherapies, as demonstrated in Figure 11. At the RP2D of 15 mg/kg, the trial observed an ORR of 33.3%. Moreover, the median PFS for the overall, 2L, and 3L+ patients was 2.8, 4.1, and 2.8 months, respectively. The median overall survival (OS) was 11.9 months, as of 3 June 2025. The 6-month OS rates for the overall, 2L, and 3L+ populations were 77.8%, 85.9%, and 70.8%, respectively. This

outcome significantly outperforms the publicly reported clinical trial data of currently available therapies for treating late-line EP-NEC. In comparison, the mOS of FOLFIRI, nivolumab as well as the combination of nivolumab and ipilimumab regimen was 8.9, 7.2 and 5.8 months, respectively, in the second-line or above treatment of EP-NEC.

Figure 11: Comparison of drug candidates in 2L+ NEC

NCT	Phase	Treatment	Patient Number	Indication	Treatment Line	ORR (%)	mPFS (m)	mOS (m)
NCT05170958	**I/II**	**LBL-024**	**45**	**EP-NEC**	**≥2L**	**33.3%**	**2.8**	**11.9**
NCT05170958	**I/II**	**LBL-024**	**21**	**EP-NEC**	**2L**	**38.1%**	**4.1**	**Not reached**
NCT04169672	II	Surufatinib + Toripalimab	21	NEC	2L	23.8%	4.1	10.9
NCT03167853	Ib	Toripalimab	40	NEN	≥2L	20.0%	2.5	7.8
NCT02820857	II	FOLFIRI	67	NEC	2L	18.3%	3.5	8.9
NCT03136055	II	Pembrolizumab	14	EP-NEC	≥2L	7.0%	1.8	7.8
NCT03591731	II	Nivolumab	83	NEC	≥2L	7.2%	1.8	7.2
		Nivolumab + Ipilimumab	87	NEC	≥2L	14.9%	1.9	5.8
NCT02955069	II	PDR001	21	GEP-NEC	≥2L	4.8%	1.8	6.8
NCT03095274	II	Durvalumab+Tremelimumab	18	GEP-NEC	2L	16.7%	2.4	5.9
NCT04400474	II	Cabozantinib+Atezolizumab	9	G3 EP-NEN	≥2L	0	2.7	5.4

Source: Company data, Frost & Sullivan Analysis, CMBIGM

In the 1L EP-NEC cohort of the Phase Ib/II clinical trial of LBL-024 in combination with chemotherapy, the 15mg/kg dose group showed a particularly promising ORR of 79.2% (19/24). Furthermore, during the dose optimization stage of the Phase II trial, an ORR of 83.3% was observed at the 15 mg/kg dosage, which is approximately twice the ORR of recommended first-line chemotherapy regimens (ORR typically 30-55%), as reported in publicly available clinical data. No DLTs were observed and the MTD was not reached up to 15 mg/kg.

LBL-024's proven efficacy in EP-NEC presents a strong case for its potential development for other NEC types, such as SCLC, and potentially as a frontline treatment. In Leads Biolabs' Phase Ib/II trial of LBL-024 in combination with chemotherapy, among 52 evaluable patients, ORR of 86.5% (45/52) was observed in the SCLC cohort, as of 5 June 2025.

Beyond NECs, LBL-024 monotherapy has also generated preliminary efficacy signals in multiple other large cancer indications, particularly BTC. In its monotherapy Phase I/II trial, among 25 evaluable patients with BTC, one achieved CR (DoR of 100 weeks) and one achieved PR, indicating an ORR of 8.0%, respectively, as of 12 February 2025, suggesting therapeutic potential in other cancer indications. Leads Biolabs also saw preliminary efficacy signals of LBL-024 monotherapy in other large cancer indications in this trial, such as NSCLC.

Pivotal-stage candidate with potential to be the first marketed 4-1BB-targeted agent and the first marketed drug for EP-NEC

As the most advanced candidate in its class, LBL-024 has the potential to be the first marketed 4-1BB-targeted agent worldwide. Having successfully completed the Phase I clinical trial of LBL-024 as monotherapy in solid tumors and the Phase II trial for EP-NEC, the Company has obtained the approval from the NMPA to initiate a single-arm pivotal trial to evaluate LBL-024 for patients with EP-NEC 3L treatment in April 2024. In the absence of a standard of care for EP-NEC, Leads Biolabs is poised to seek an accelerated and conditional marketing approval for LBL-024 based on the pivotal trial's outcomes. The Company enrolled the first patient in this trial in July 2024. Subject to the clinical progress, it expects to submit a BLA to the NMPA by the third quarter of 2026. This clinical development strategy is designed to expedite LBL-024's entry to the market, cementing its leading position at the

forefront of 4-1BB-targeted therapies. Moreover, if approved, LBL-024 could become the first drug to receive approval for treating EP-NEC globally, offering an effective treatment option for this cancer with highly unmet medical need.

In parallel, Leads Biolabs is dedicated to expanding LBL-024's therapeutic potential and advancing its clinical development and registration for the treatment of other indications. In addition to EP-NEC, LBL-024 also demonstrated strong potential in treating other NEC types, such as SCLC, and potentially as a frontline treatment. Additionally, based on its preliminary efficacy signals in multiple prevalent cancer types, including NSCLC, BTC and HCC, the Company has initiated a Phase Ib/II trial to evaluate the use of LBL-024 in combination with the standard of care for SCLC, NSCLC and other solid tumors. In July 2025, first patient in the Phase II trial for LBL-024 in combination with SoC for NSCLC was enrolled. The Company also plans to commence Phase II studies of LBL-024 in combination with SoC for the treatment of BTC, HCC, melanoma and OC in 3Q25, TNBC in 2H25, and ESCC and GC in 1H26. In addition, Leads Biolabs may seek collaboration opportunities with large industry players for the overseas clinical development and commercialization of LBL-024.

Promising clinical trial results as monotherapy and in combo with chemo for EP-NEC and SCLC

Phase I/II clinical trial of LBL-024 monotherapy in solid tumors

Leads Biolabs commenced the Phase I/II study (NCT05170958) of LBL-024 monotherapy in January 2022 in China, with the Phase II initiated in June 2023. In February 2024, Leads Biolabs submitted the pivotal study application for EP-NEC to the NMPA and received approval in April 2024.

Trial design. The Phase I clinical trial of LBL-024 is a single-arm, open-label, dose escalation study conducted in China, designed to evaluate the safety, tolerability, pharmacokinetic (PK), immunogenicity, and preliminary efficacy in patients suffering with advanced malignant tumors. The patients are assigned into seven cohorts, receiving LBL-024 at 0.2 mg/kg to 25 mg/kg once every three weeks (Q3W). The primary objectives of the trial are to access the DLT of LBL-024, and determine the MTD and/or RP2D.

Meanwhile, the Phase II trial is a single-arm, open-label, indication expansion Phase II trial in China to further evaluate the efficacy, safety, PK profile and immunogenicity of LBL-024. This trial involves patients with advanced EP-NEC and other solid tumor types, including biliary tract carcinoma (BTC) and NSCLC, organized into four distinct treatment cohorts. Each patient group receives an administered dose of LBL-024 at 15 mg/kg Q3W. The primary measure for success in this phase is the IRC-evaluated ORR.

Figure 12: Baseline characteristics of Phase I/II trial of LBL-024 monotherapy

Parameter		Phase I, n (%)	Phase IIa, n (%)
		n=64	n=111
Age	Median	58 yrs.	58 yrs.
	Range	32 yrs. to 72 yrs.	28 yrs. to 75 yrs.
Gender	Male	36 (56.3%)	74 (66.7%)
	Female	28 (43.7%)	37 (33.3%)
ECOG	0	3 (4.7%)	16 (14.4%)
	1	61 (95.3%)	95 (85.6%)
Prior Treatments	I/O Treatments	16 (25.0%)	48 (43.2%)
Cancer Types	Extra-pulmonary Neuroendocrine Carcinoma (EP-NEC)	28 (43.8%)	34 (30.6%)
	Biliary Tract Cancers (BTC)	11 (17.2%)	20 (18.0%)
	Others (OC, NSCLC, HCC, CRC, ESCC, etc.)	25 (39.1%)	57 (51.4%)

Source: Company data, CMBIGM.

Trial status. Leads Biolabs completed the Phase I trial in June 2023. A total of 64 patients were enrolled in this trial including cohorts for EP-NEC, ovarian cancer (OC), biliary tract cancer, NSCLC, and other solid tumors. Building on the promising data, the Company proceeded to the Phase II clinical trial, with enrollment completed in December 2023, with a total of 111 patients enrolled including cohorts for EP-NEC, NSCLC, biliary tract cancer, and other solid tumors.

Safety results. As of 3 June 2025, Leads Biolabs' clinical study has shown promising safety results. No DLT was observed, and the MTD was not reached at a dosage of up to 25 mg/kg. Among the participants, 139 out of 175 (79.4%) experienced TRAEs of all grades. 38 (21.7%) of these patients experienced TRAEs of grade≥3. The majority of adverse events were grades 1-2, indicating a manageable safety profile of LBL-024. The most common TRAEs, affecting more than 15% of patients, included anemia (34.4%), elevated AST (32.6%), increased ALT (28.0%), and leukopenia (20.0%).

Figure 13: The safety data observed in the Phase I/II trial of LBL-024 monotherapy

	Phase I (n=64)								Phase IIa (n=111)
Adverse events	0.2 mg/kg (n=1)	0.8 mg/kg (n=3)	3.2 mg/kg (n=13)	6 mg/kg (n=7)	10 mg/kg (n=12)	15 mg/kg (n=12)	25 mg/kg (n=16)	Total (n=64)	15 mg/kg (n=111)
TEAE	1 (100.0%)	3 (100.0%)	12 (92.3%)	7 (100.0%)	12 (100.0%)	12 (100.0%)	16 (100.0%)	63 (98.4%)	100 (90.1%)
TRAE	1 (100.0%)	3 (100.0%)	10 (76.9%)	5 (71.4%)	11 (91.7%)	11 (91.7%)	16 (100.0%)	57 (89.1%)	82 (73.9)
SAE	0 (0.0%)	2 (66.7%)	5 (38.5%)	3 (42.9%)	5 (41.7%)	3 (25.0%)	3 (18.8%)	21 (32.8%)	37 (33.3%)
TR-SAE	0 (0.0%)	2 (66.7%)	3 (23.1%)	1 (14.3%)	3 (25.0%)	2 (16.7%)	1 (6.3%)	12 (18.8%)	18 (16.2)
≥Grade 3 AE	0 (0.0%)	2 (66.7%)	6 (46.2%)	5 (71.4%)	7 (58.3%)	4 (33.3%)	4 (25.0%)	28 (43.8%)	44 (39.6)
≥Grade 3 TRAE	0 (0.0%)	2 (66.7%)	4 (30.8%)	1 (14.3%)	5 (41.7%)	3 (25.0%)	3 (18.8%)	18 (28.1%)	20 (18.0)
TRAE leading to treatment interruption	0 (0.0%)	1 (33.3%)	3 (23.1%)	1 (14.3%)	5 (41.7%)	3 (25.0%)	1 (6.3%)	14 (21.9%)	27 (24.3)
TRAE leading to treatment discontinuation	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (8.3%)	2 (16.7%)	1 (6.3%)	4 (6.3%)	3 (2.7)

Source: Company data (as of 3 June 2025), CMBIGM
Note: TEAE refers to treatment emergent adverse events; TRAE refers to treatment-related adverse events; SAE refers to serious adverse events; TR-SAE refers to treatment-related serious adverse events; AE refers to adverse events.

In the combined Phase I/II trial with 175 patients (64 patients in Phase I, 111 patients in Phase II), the most adverse events are Grade 1 or 2 and manageable. Out of 175 patients, only 1.1 (2/175) and 0.6% (1/175) patients experienced ≥3 grade adverse events of increases in AST and ALT levels, respectively, both of which are key indicators of liver toxicity. The most frequently reported treatment-emergent adverse events (≥10%) included anemia (34.3%), increased AST levels (32.6%), increased ALT levels (27.4%), leukopenia (20.0%), hypoalbuminemia (16.6%), hyponatremia (16.0%), thrombocytopenia (14.9%), neutropenia (14.9%), hypertriglyceridemia (14.3%), asthenia (13.1%), hypokalemia (13.1%), proteinuria (13.1%), increased blood bilirubin (13.1%), decreased appetite (11.4%), and pyrexia (10.9%).

Efficacy results. As of 3 Jun 2025, among the 45 evaluable patients with 2L/3L+ EP-NEC, 3 of these patients achieved CR, 12 achieved PR and 8 maintained SD, resulting in an ORR of 33.3% and a DCR of 51.1%. At the RP2D of 15 mg/kg, the ORR was 33.3% and the DCR was 48.5% in 2L patients. Moreover, the median DoR was 5.3 months, with 3.8 months for the 2L patients and 7 months for the 3L+ patients. The median PFS for the overall, 2L, and 3L+ patients was 2.8, 4.1, and 2.8 months, respectively. The median follow-up period was 23.6 months, and the mOS was 11.9 months. The 6-month OS rates for the overall, 2L, and 3L+ populations were 77.8%, 85.9%, and 70.8%, respectively.

In the BTC patient cohort of the same study, 25 patients were evaluated for treatment efficacy. The ORR was 8.0%, and the DCR reached 52.0%, demonstrating certain level of disease stabilization. Noteworthy is a case of CR with a DoR of 100 weeks. Another patient in this group showed prolonged benefit with a PR lasting 9.6 months, suggesting therapeutic potential in other cancer indications.

Conclusion. LBL-024 has demonstrated favorable safety profile in patients with advanced solid tumors, and the preliminary efficacy results suggest its robust antitumor activities in advanced EP-NEC and therapeutic potential for other tumor types.

Phase Ib/II clinical trial of LBL-024 in combination with etoposide and platinum-based chemotherapy in EP-NEC and SCLC

The company launched a Phase Ib/II (NCT06157827) study of LBL-024 in combination with etoposide and platinum-based chemotherapy in January 2024 in China for the first-line treatment of advanced EP-NEC and SCLC.

Trial design. The Phase Ib trial is a single-arm, open-label, dose-escalation study conducted in China, aimed at assessing the safety, tolerability, efficacy, PK characteristics, and immunogenicity of LBL-024 in combination with etoposide and platinum-based chemotherapy for patients with advanced EP-NEC and SCLC. Patients participating in this study are divided into three cohorts, each receiving doses of LBL-024 ranging 6 mg/kg, 10 mg/kg and 15 mg/kg Q3W. Based on the specific conditions of each participant, investigators have the discretion to choose between two chemotherapy regimens: etoposide plus cisplatin (EP) or etoposide plus carboplatin (EC). The primary outcomes measured in this trial include the monitoring of adverse events, DLT, and abnormalities in laboratory test results.

The Phase II trial is a randomized, single-arm, open-label, dose-expansion study conducted in China, focusing on evaluating the efficacy, safety, and immunogenicity of LBL-024 in combination with etoposide and platinum-based chemotherapy in patients with advanced EP-NEC and SCLC. In this phase, patients are administered LBL-024 Q3W in combination with either etoposide plus cisplatin (EP) or etoposide plus carboplatin (EC) at two different dosage levels. The RP2D of LBL-024 will be determined by the Safety Monitoring Committee. The administration of chemotherapy will adhere to the protocol established in Phase Ib. The primary endpoint for this trial is the ORR.

Trial status. As of 5 June 2025, the Company has enrolled a total of 108 subjects in this Phase Ib/II trial. Enrollment for the EP-NEC cohort was completed in December 2024. Leads Biolabs is currently recruiting patients for the SCLC cohort and has 52 evaluable patients as of the cutoff date.

Safety results. As of 5 June 2025, among 108 patients with 1L NEC (including EP-NEC and SCLC) that were enrolled to receive LBL-024 at doses of 6, 10 and 15 mg/kg in combination with EP chemotherapy, no DLT was observed, and the MTD was not reached up to 15 mg/kg.

Efficacy results. As of 5 June 2025, among 52 evaluable patients in the EP-NEC cohort of the Phase Ib/II trial of LBL-024, 3 achieved CR and 36 achieved PR, demonstrating an encouraging ORR of 75.0% (39/52). As of 5 Jun 2025, among 52 evaluable patients, ORR of 86.5% (45/52) was observed in the SCLC cohort.

Conclusion. The clinical data from the Phase Ib/II trial of LBL-024 in combination with etoposide and platinum-based chemotherapy has demonstrated promising safety and preliminary efficacy profile, and supports continued development for the treatment of NECs including both EP-NEC and SCLC.

Detailed data readout of LBL-024 in 1L EP-NEC at 2025 ASCO

As of 5 Jun 2025, the updated Phase Ib/II data for LBL-024 in first-line EP-NEC was further reported at 2025 ASCO. In 52 efficacy-evaluable patients, the ORR across all dose levels was 75.0%, significantly outperforming historical ORR data (typically 30%-55%) with chemotherapy alone. The 15 mg/kg in dose optimization demonstrated the strongest anti-tumor activity, achieving an ORR of 83.3%. As of 15 April 2025, with a median follow-up of 8.2 months, PFS data remains immature, but trends indicate promising durability across all the dose groups. In the Phase Ib dose escalation stage, no DLTs were observed. Most TEAEs were Grade 1–2 and manageable, primarily associated with chemotherapy, including hematologic toxicity and nausea. No unexpected safety signals were identified.

Figure 14: Clinical data of chemotherapy in 1L EP-NEC

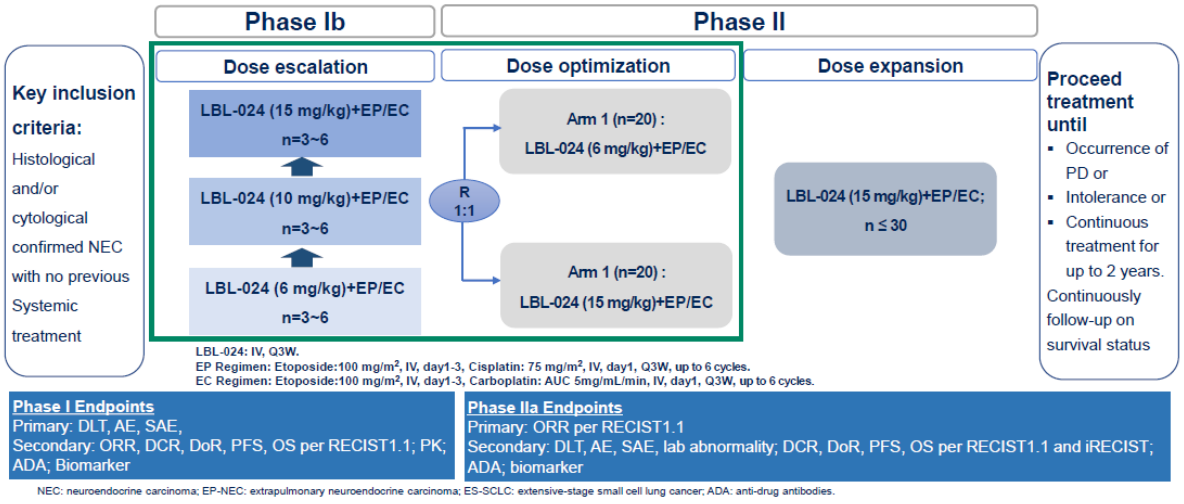
No.	Type	Treatment	Line	Size	Indication	ORR(%)	mPFS(m)	mOS(m)
/	Meta-analysis[1]	Platinum-doublet regimen	1L	1157	GEP-NEC	49.1 %	5.4 m	12.9 m
jRCTs031180005	Phase 3[2]	EP	1L	84	NEC (Digest system)	54.5 %	5.6 m	12.5 m
		IP		86		52.5 %	5.1 m	10.9 m
NCT03168594	Phase 2[3]	EP	1L	33	GEP-NEC	42.4 %	6.4 m	11.3 m
		IP		33		42.4 %	5.8 m	10.2 m
2019	Retrospective[4]	EC	1L	98	EP-NEC	47.9 %	5.8 m	11.5 m

EP: Etoposide plus cisplatin; IP: Irinotecan plus cisplatin; EC: carboplatin plus etoposide.

Reference: [1] Ohmoto A. *Discov Oncol*. 2022; [2] Morizane C. *JAMA Oncol*. 2022; [3] Zhang P, et al. *Cancer*. 2020; [4] Frizziero M.*Neuroendocrinology*. 2019.

Source: Company data, ASCO slides, CMBIGM. Note: Etoposide/platinum based chemotherapy remains the recommended 1 L treatment for advanced EP NEC.

Figure 15: Study design and major clinical results of LBL-024 + chemo in 1L EP-NEC



NEC: neuroendocrine carcinoma; EP-NEC: extrapulmonary neuroendocrine carcinoma; ES-SCLC: extensive-stage small cell lung cancer; ADA: anti-drug antibodies.

		Phase Ib Dose escalation			Phase II Dose optimization		Total
		6 mg/kg (N=3)	10 mg/kg (N=6)	15 mg/kg (N=6*)	6 mg/kg (N=19)	15 mg/kg (N=18)	N=52
BOR#,n (%)	CR	0	0	0	0	1 (5.6)	1 (1.9)
	PR	2 (66.7)	4 (66.7)	4 (66.7)	14 (73.7)	14 (77.8)	38 (73.1)
	SD	1 (33.3)	1 (16.7)	0	4 (21.1)	3 (16.7)	9 (17.3)
	PD	0	1 (16.7)	2 (33.3)	1 (5.3)	0	4 (7.7)
ORR#, n (%)		**2 (66.7)**	**4 (66.7)**	**4 (66.7)**	**14 (73.7)**	**15 (83.3)**	**39 (75.0)**
DCR, n (%)		**3 (100.0)**	**5 (83.3)**	**4 (66.7)**	**18 (94.7)**	**18 (100.0)**	**48 (92.3)**

6 PR patients have not been comfirmed by data cutoff.

Data Cutoff date: April 15th, 2025, data from China. *2 patients with SCLC, 1 with MiNEN and 3 with EP-NEC. BOR: Best Overall Response; CR: Complete Response; PR: Partial Response; SD: Stable Response; PD: Progressive Disease.

	6 mg/kg, n(%) (n=23)	10 mg/kg, n(%) (n=6)	15 mg/kg, n(%) (n=26)	Total, n(%) (N=55)
Any TEAEs	23 (100.0)	6 (100.0)	26 (100.0)	55 (100.0)
TRAEs(Related to treatment)	22 (95.7)	6 (100.0)	26 (100.0)	54 (98.2)
≥Grade 3 TEAEs	21 (91.3)	5 (83.3)	23 (88.5)	49 (89.1)
≥Grade 3 TRAEs(Related to treatment)	19 (82.6)	5 (83.3)	20 (76.9)	44 (80.0)
SAEs	12 (52.2)	2 (33.3)	12 (46.2)	26 (47.3)
TR-SAEs(Related to treatment)	10 (43.5)	2 (33.3)	8 (30.8)	20 (36.4)
irAEs	7 (30.4)	2 (33.3)	9 (34.6)	18 (32.7)
≥Grade 3 irAEs	1 (4.3)	2 (33.3)	4 (15.4)	7 (12.7)
TRAEs leading to treatment interruption	15 (65.2)	5 (83.3)	15 (57.7)	35 (63.6)
TRAEs leading to treatment discontinuation	0 (0.0)	0 (0.0)	2 (4.7)	2 (3.6)
TRAEs leading to death*	0 (0.0)	0 (0.0)	1 (3.8)	1 (1.8)

*One treatment-related death, which occurred after the first cycle. The event was a G4 leukopenia, pulmonary embolism and septic shock that led to a fatal outcome. Data Cutoff date: April 15th, 2025, data from China.

Preferred Terms, n (%)	Total, n=55	
	Any grade	≥Grade 3
Leukopenia	44 (80.0)	20 (36.4)
Neutropenia	44 (80.0)	34 (61.8)
Anemia	41 (74.5)	12 (21.8)
Thrombopenia	36 (65.5)	14 (25.5)
Nausea	29 (52.7)	2 (3.6)
AST increased	20 (36.4)	2 (3.6)
Asthenia	19 (34.5)	0
Alopecia	19 (34.5)	0
Proteinuria	18 (32.7)	0
ALT increased	16 (29.1)	1 (1.8)
Constipation	16 (29.1)	0

Preferred Terms, n (%)	Total, n=55	
	Any grade	≥Grade 3
Hyponatremia	13 (23.6)	1 (1.8)
Weight decreased	13 (23.6)	0
Hypertriglyceridemia	13 (23.6)	0
Decreased appetite	13 (23.6)	0
Hypokalemia	12 (21.8)	1 (1.8)
Hyperglobulinemia	12 (21.8)	0
Vomiting	10 (18.2)	1 (1.8)
Pyrexia	9 (16.4)	0
Hypercholesterolemia	8 (14.5)	0
Insomnia	7 (12.7)	0
Hyperglycemia	6 (10.9)	1 (1.8)
Rash	6 (10.9)	0

Source: Company data, ASCO slides, CMBIGM

Comprehensive clinical development plan starting with EP-NEC and SCLC

Leads Biolabs plans to develop LBL-024 both as monotherapy and as a backbone for combination therapy that have potential to address significant unmet medical needs in global market.

As of September 2025, LBL-024 is in multiple early-stage trials for the treatment of NEC, NSCLC, OC, Melanoma, BTC, HCC, etc.

Figure 16: Clinical trials of LBL-024

Trial ID	Indication	Regimen	Trial phase	First posted	Completion date	Patient no.
NCT07111546	BTC, HCC	LBL-024 + chemo or durvalumab (PD-L1 mAb) + chemo or LBL-024 + bevacizumab	Phase II	2025-08-08	2026-12-26	172
NCT07099430	Melanoma	LBL-024 mono, LBL-024 + LBL-007 (LAG3 mAb), LBL-024 + toripalimab	Phase Ib/II	2025-08-01	2027-12-30	200
NCT07042802	Ovarian Cancer	LBL-024 + chemo, chemo mono	Phase Ib/II	2025-06-29	2028-03-20	110
NCT06783647	NSCLC	LBL-024 + docetaxel, LBL-024 + docetaxel + bevacizumab	Phase II	2025-01-20	2026-12-24	230
NCT06157827	1L EP-NEC	LBL-024 + chemo	Phase I/II	2023-12-06	2027-07-20	178
NCT05170958	solid tumors	LBL-024	Phase I/II	2021-12-28	2026-12-01	396

Source: PharmCube, CMBIGM

Note: Data as of Sep 2025.

Figure 17: Clinical development plan for LBL-024 as per prospectus

Indication	Mono/Combo	Clinical trial stage	Location	(Expected) first patient enrollment date	Expected BLA submission date
3L+ EP-NEC	Mono	Registrational	China	July 2024	Q3 2026
1L EP-NEC	Combo (with EP/CP)	Phase Ib/II	China	January 2024	2029
1L SCLC	Combo (with EP/CP)	Phase Ib/II	China	January 2024	2029
NSCLC and other solid tumors	Combo (with SOC)	Phase II	China	H2 2025	2030

Source: Company prospectus, CMBIGM

Leads Biolabs' clinical development plan for LBL-024 incorporates a fast-to-market strategy targeted at 3L+ EP-NEC. Leads Biolabs is conducting a single-arm registrational trial to evaluate LBL-024 monotherapy in late-line EP-NEC. The Company expects to submit the BLA by the third quarter of 2026. The Company expects to give a readout for the Ph2 trial in 1L EP-NEC in 2026.

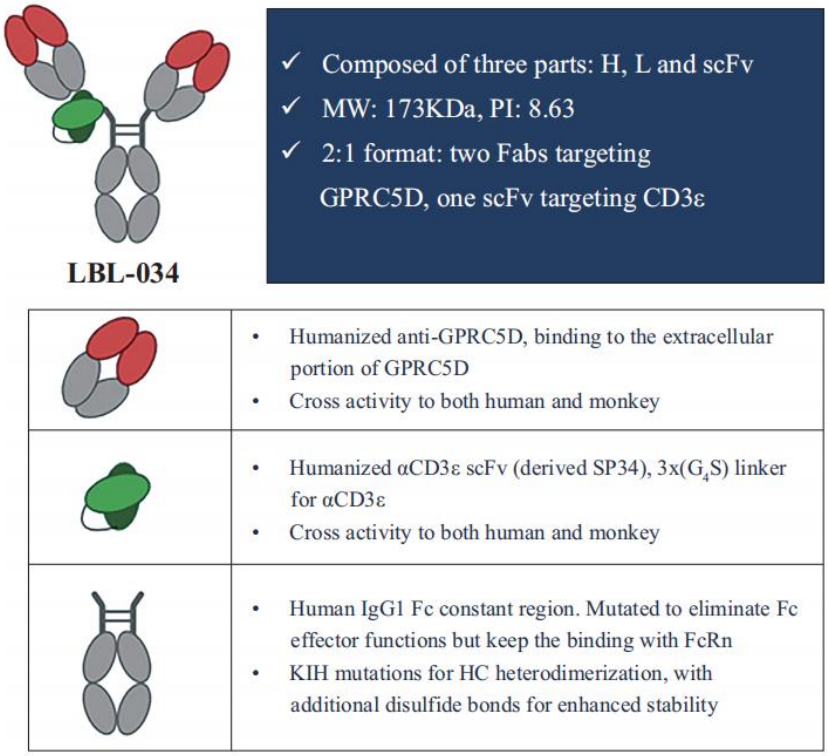
Leads Biolabs is focusing on indication expansion for LBL-024, specifically in combination with chemotherapy. Considering that SCLC is a specific form of NEC, the Company is positioning LBL-024 into a potential first-line combination treatment for SCLC, which represents a larger patient pool. The Company anticipates to complete the Phase Ib/II trial of LBL-024 in combination with chemotherapy in 2H25.

Beyond EP-NEC and SCLC, Leads Biolabs plans to further investigate the potential of LBL-024 in other solid tumors, i.e. in combination therapies of LBL-024 with SOC for 1L BTC and 2L NSCLC. Leads Biolabs is also committed to expand LBL-024 into ESCC, HCC, GC and other solid tumors. In July 2025, first patient in the Phase II trial for LBL-024 in combination with SoC for NSCLC was enrolled. The Company also plans to commence Phase II studies of LBL-024 in combination with SoC for the treatment of BTC, HCC, melanoma and OC in 3Q25, TNBC in 2H25, and ESCC and GC in 1H26.

LBL-034 (GPRC5D/CD3), the second most advanced GPRC5D-targeted CD3 T-cell engager globally with a favorable safety profile

LBL-034 is a humanized, bispecific T-cell engager that specifically targets GPRC5D and CD3, and it is currently being developed in a Phase I/II trial for the treatment of relapsed/refractory MM in China. Benefiting from the unique structural design, LBL-034 has induced lower levels of cytokine release compared to the analog of TALVEY® (talquetamab) by Janssen Biotech, which is approved for MM in the U.S. Including TALVEY®, LBL-034 is the second most clinically advanced GPRC5D-targeted CD3 T-cell engager globally. T-cell engagers have demonstrated significant potential in treating various types of cancer, especially "cold tumors" that do not respond well to immune-checkpoint inhibitors; however, they are often associated with serious safety concerns, such as CD3-induced CRS. To address these issues, the Company's proprietary LeadsBody platform has been utilized to refine the selection of various molecular formats of the Company's T-cell engager candidates, aiming to achieve an optimal balance between safety and efficacy. Further, LBL-034 obtained the ODD from the FDA for the treatment of MM in October 2024.

Figure 18: The molecular structure of LBL-034



Source: Company data, CMBIGM

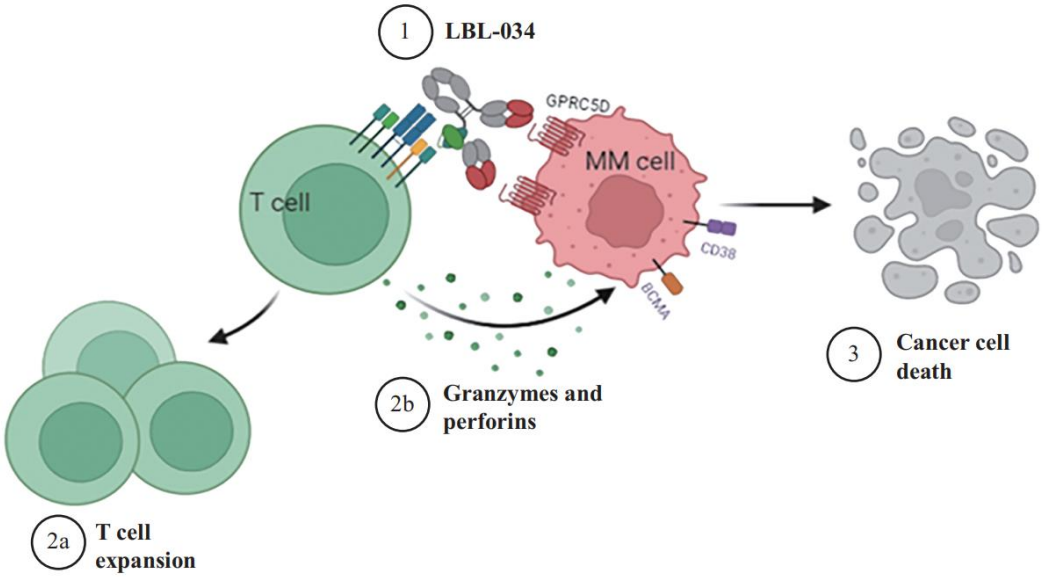
GPRC5D is a type C 7-pass transmembrane receptor protein that is selectively overexpressed on malignant plasma cells in MM, while exhibiting minimal expression in normal tissues such as the skin and testes, and very low levels in normal B cells and plasma cells. This selective expression makes GPRC5D an ideal target for immunotherapy. This specific expression pattern allows for a targeted approach to attack cancer cells while minimizing harm to normal cells. CD3, on the other hand, is a protein complex and T cell co-receptor essential for activating both cytotoxic T cells and T helper cells, playing a critical role in the immune response against tumors.

LBL-034, a bispecific antibody, was designed to capitalize on these properties by targeting both GPRC5D and CD3, thereby activating T-cells against cancer cells. This antibody comprises three components: two Fabs that bind with high affinity to GPRC5D on tumor cells, one scFv that targets CD3 on T cells with low affinity, and a mutant IgG1 Fc portion. The strategic layout and spatial configuration of the CD3-targeting scFv relative to the GPRC5D-targeting Fab were meticulously engineered to ensure that the scFv is physically obstructed by the Fab, preventing it from binding to CD3 unless the

antibody also concurrently binds to a GPRC5D-expressing cell. This design enhances the specificity of T-cell activation, significantly reducing the risk of on-target off-tumor effects and improving the therapeutic efficacy of LBL-034 in treating MM.

By simultaneously binding to CD3 on T cells and the tumor-associated antigen GPRC5D on cancer cells, LBL-034 brings T cells into close proximity with cancer cells, effectively activating the T cells to attack and kill the targeted cancer cells. This mechanism differs from other T cell-based immunotherapies, such as PD-1 inhibitors, as it harnesses the power of the immune response to selectively attack cancer cells independent of T-cell receptor recognition of tumor antigens, offering a highly targeted and effective approach for cancer treatment. Moreover, the 2:1 format of the molecule construct utilizes the steric hindrance effects of the GPRC5D Fabs, coupled with the fine-tuned affinity ratio for the two targets. This design minimizes the risk of off-target toxicity, thereby enhancing the safety profile of LBL-034.

Figure 19: The mechanism of action of LBL-034



Source: Company data, CMBIGM

MM is typically challenging to cure, with treatment goals focused on achieving and maintaining remission, improving quality of life, and prolonging OS. Currently, the first-line therapy includes a combination of the anti-CD38 monoclonal antibody daratumumab with bortezomib, lenalidomide, and dexamethasone. While this regimen has shown efficacy, it also has limitations such as significant toxicity, the potential for drug resistance, and the eventual relapse in many patients. For relapsed or recurrent multiple myeloma patients, there remains significant unmet clinical needs for effective later-line treatments. One of the primary benefits of targeting GPRC5D/CD3 bispecific antibodies is the reduced incidence of side effects, including lower infection rates and fewer immune-related adverse reactions such as cytokine release syndrome and neurotoxicity. The increasing incidence of multiple myeloma and limitations of current treatments highlight a significant market opportunity for therapies like GPRC5D/CD3 bispecific antibodies, which offer improved safety profiles and significantly enhanced cytotoxicity when combined with immunomodulatory drugs, suggesting a potent and effective approach for a broad population of relapsed or refractory patients.

LBL-034 is the second most clinically advanced GPRC5D-targeted CD3 T-cell engager globally. talquetamab (TALVEY) by Janssen Biotech was approved in August 2023 for the treatment of patients with heavily pretreated multiple myeloma, representing the only approved GPRC5D/CD3 bispecific antibody drug to date.

Figure 20: Development of GPRC5D/CD3 related antibodies globally

Drug name	Target	Company	China stage	US stage
Talquetamab/TALVEY	CD3; GPRC5D	Johnson & Johnson; Genmab	Approved	Approved
QLS32015	CD3; GPRC5D	Qilu	Phase II	-
LBL-034	CD3; GPRC5D	Leads Biolabs	Phase I/II	-
forimtamig (terminated)	CD3; GPRC5D	Roche	IND	-
IBI3003	CD3; GPRC5D; BCMA	Innovent	Phase I/II	-
MBS314	CD3; GPRC5D; BCMA	KYinno Biotech; Mabworks	Phase I/II	IND
JNJ-79635322	CD3; GPRC5D; BCMA	Janssen Biotech	--	Phase I
SCR-8572	CD3; GPRC5D; BCMA	Simcere; AbbVie	Phase I	Phase I
SHR-9539	CD3; GPRC5D	Hengrui	Phase I	-
QLS4131	CD3; GPRC5D; BCMA	Qilu	Phase I	IND
TQB2029	CD3; GPRC5D	Chia Tai Tianqing Pharma	Phase I	-
CM380	CD3; GPRC5D		IND	-

Source: PharmCube, CMBIGM

Note: Data as of Sep 2025.

Figure 21: Details of TALVEY®

Drug Name	Brand Name	Target	Company	Indications	Approval Date	Treatment Cost
talquetamab-tgvs	TALVEY®	GPRC5D/CD3	Janssen Biotech	r/r MM who have received at least four prior lines of therapy	2023-08-09	US$270,000 to US$360,000 based on the need for 6 to 8 months of treatment in the U.S.

Source: Company data, CMBIGM

Note: Industry information as of 28 May 2025

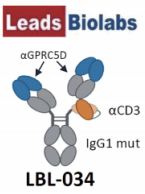
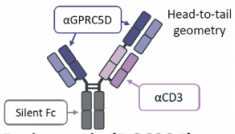
Robust competitive advantages based on differentiated drug design

Optimized 2:1 asymmetrical structure that leads to unique conditional activation of T cells and a favorable safety profile

LBL-034's distinct molecular structure, characterized by a 2:1 format, differentiated affinities, steric hindrance, and mutant IgG1 abolishing FcγR binding along with its ability to induce both antibody-dependent cell-mediated cytotoxicity (ADCC) and complement-dependent cytotoxicity (CDC) effects, enables conditional T cell activation in the presence of GPRC5D+ cells, thereby reducing off-target CD3 engagement and minimizing the risk of CRS and immunotoxicity.

The figure below compares LBL-034 with talquetamab, highlighting LBL-034's highly differentiated GPRC5D/CD3 T cell engager.

Figure 22: Selected information of LBL-034 compares to talquetamab and forimtamig

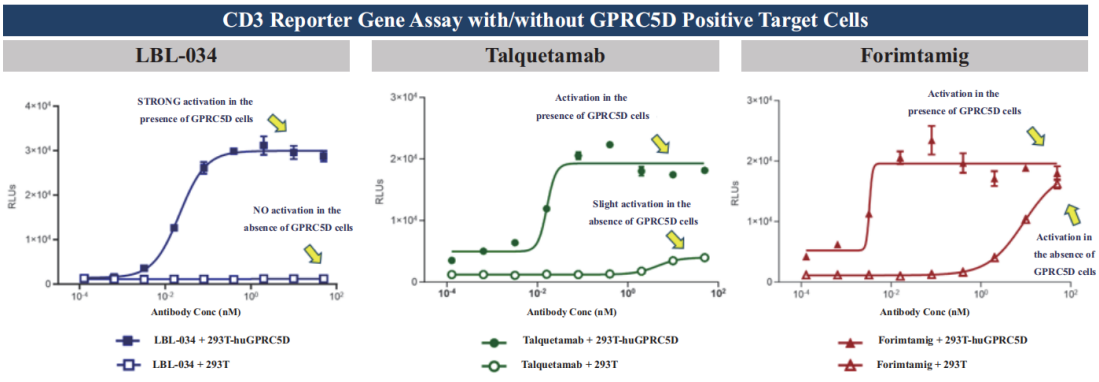
	LBL-034	Talquetamab	Forimtamig (RG6234)
			
Format	**2:1, αCD3 is scFv**	1:1, αCD3 is Fab	2:1, αCD3 is Fab
Fc Type	IgG1 mut (No Fc function)	IgG4 mut (No Fc function)	IgG1 mut (Silent Fc)
Binging 293T GPRC5D cell (EC_{50})	0.4588 nM	1.4580 nM	0.3241 nM
Affinity to CD3 protein (KD)	1.03E-08 M	1.46E-08 M	4.78E-09 M
Binding Jurkat Cells (EC_{50})	**Very Weak**	10.82 nM	17.23 nM
Cell-Cell Conjugation	+++	+++	+++
CD3 Reporter Gene Activity (EC_{50})	0.021 nM	0.011 nM	0.003 nM
T cells Activation	**Conditional Activation**	Non-specific at High Concentrations	Non-specific at High Concentrations
T cells Viability	++	++	+
T cell Dependent Cellular Cytotoxicity	++	+	+++
CRS Risk (in vitro)	+	++	+++
% TGI in H929 PBMC mouse model	0.3 mpk, 63% 3 mpk, 100%	0.3 mpk, 37% 3 mpk, 20%	0.3 mpk, 101% 3 mpk, 103%

Note: Preclinical data of talquetamab and forimtamig in the above table was generated from their respective preclinical studies according to publicly available source, not from head-to-head studies with LBL-034.

Source: Company data, Frost & Sullivan Analysis, CMBIGM

As illustrated by the figures below, compared to talquetamab and forimtamig, both of which are GPRC5D/CD3 T-cell engaging bispecific antibodies, LBL-034 demonstrates conditional activation of T cells only in the presence of GPRC5D+ target cells, as shown in CD3 reporter gene assays.

Figure 23: LBL-034's conditional activation of T cells in GPRC5D positive cells compared to talquetamab and forimtamig

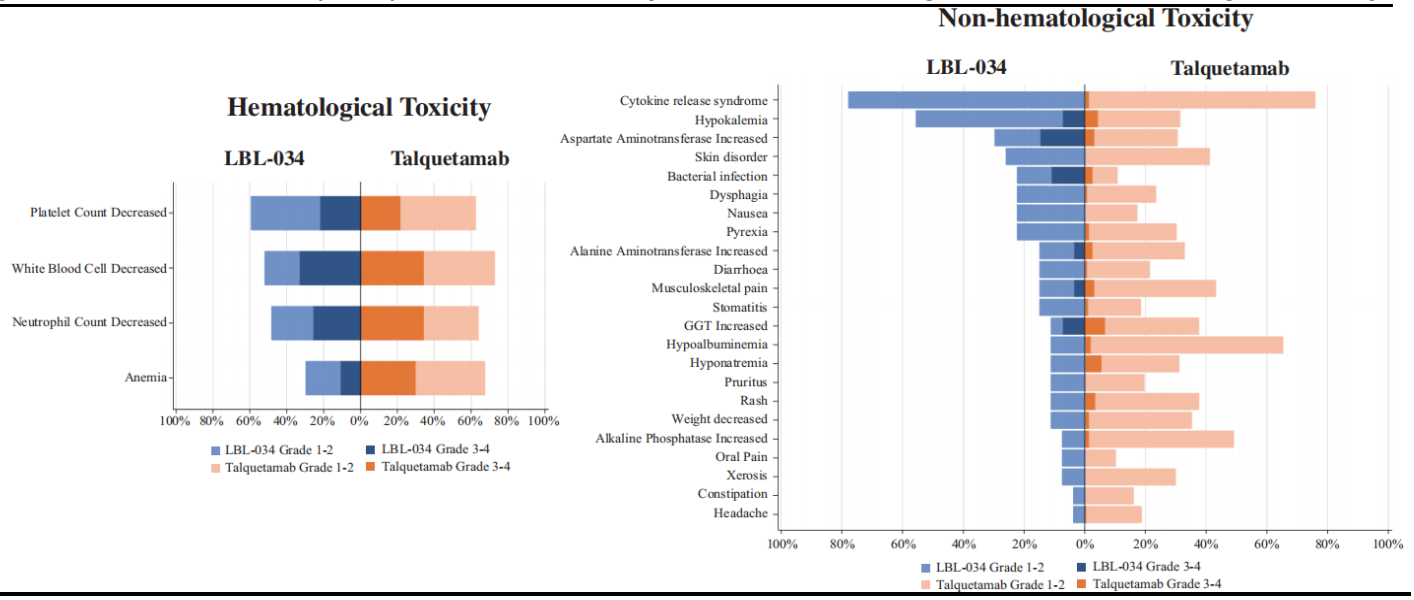


Source: Company data, CMBIGM

Toxicology studies indicate that LBL-034 is well tolerated with a NOAEL of 50 mg/kg and no evident accumulation effects after repeated administration. Positive safety outcomes in clinical trials include the absence of DLT up to 800 μg/kg. The most common TEAEs were Grade 1 to 2 and were manageable. CRS was observed up to a dosage of 800 μg/kg, no Grade 3 or higher CRS or ICANS was observed, and MTD was not reached.

LBL-034 has also exhibited a more encouraging safety profile in its Phase I/II trial compared to talquetamab according to publicly reported clinical data, as shown in the following diagrams which summarize common TEAEs (≥10%) of these two drug candidates in relation to hematological and non-hematological toxicity:

Figure 24:Common TEAEs (≥10%) of LBL-034 and talquetamab in hematological and non-hematological toxicity

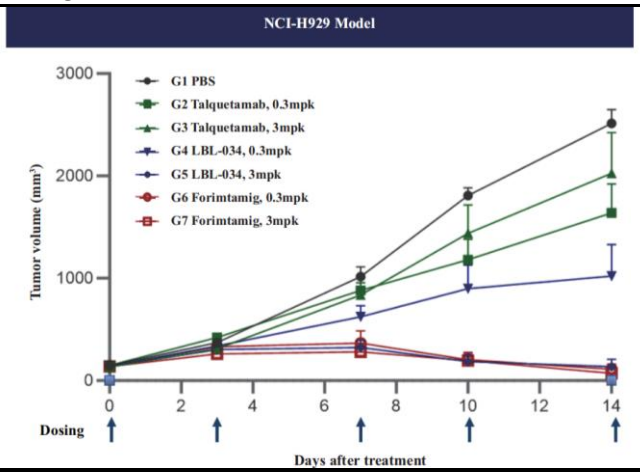


Source: Company data, CMBIGM. Notes: The safety comparing to Talquetamab is not based on a head-to-head study.

Strong antitumor activity in preclinical study and promising efficacy signal observed in the early clinical trial

LBL-034 effectively redirects and activates T cells to target GPRC5D+ cancer cells, exhibiting higher GPRC5D binding affinity and potency while being less prone to inducing T cell exhaustion and cell death. The figure below illustrates the strong, dose-dependent antitumor activity of LBL-034 in the NCI-H929 mouse model with low-to-mid GPRC5D expression. Compared to talquetamab and forimtamig, LBL-034 demonstrates superior efficacy in reducing tumor volume at both 0.3 mpk and 3 mpk doses, underscoring its potential as a highly effective therapeutic agent.

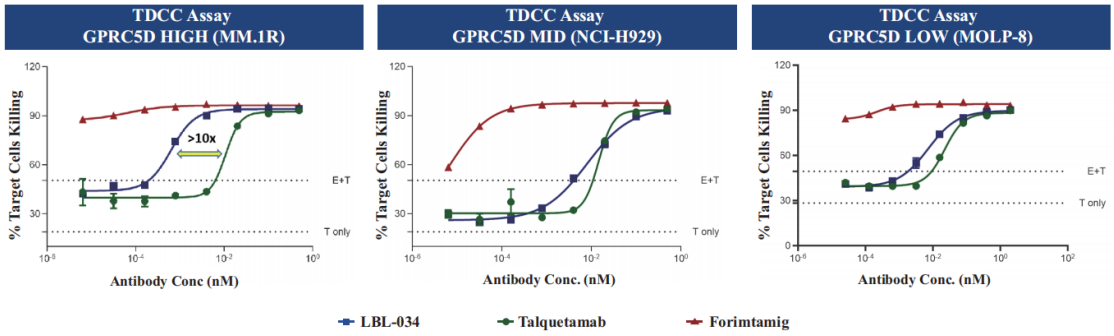
Figure 25:Antitumor activity of LBL-034 in targeting GPRC5D+ cancer cells compared to talquetamab and forimtamig



Source: Company data, CMBIGM

The data below demonstrate that LBL-034 exhibits robust, target-dependent antitumor activity across high, mid, and low GPRC5D-expressing cells. Compared to talquetamab and forimtamig, LBL-034 consistently shows superior target cell killing, highlighting its potential as a promising therapeutic agent.

Figure 26:The results of TDCC assays for GPRC5D expression levels in various cell lines (MM.1R, NCI-H929, MOLP-8)



Source: Company data, CMBIGM
Note: Roche's development of forimtamig was terminated.

Strong clinical trial results for the treatment of multiple myeloma (MM)

Phase I/II clinical trial of LBL-034 monotherapy

Overview. Leads Biolabs commenced a Phase I/II study of LBL-034 monotherapy for the treatment of MM in November 2023 in China.

Trial design. The Phase I trial is a single-arm, open-label, dose-escalation and dose-expansion study conducted in China. This trial also aims to determine the RP2D. Patients are divided into seven cohorts, with doses ranging from 10 μg/kg to 1,500 μg/kg Q2W. The primary endpoints of this phase include monitoring adverse events, determining DLT and the MTD. The Phase II trial is a single-arm and open-label trial in China, where the efficacy, safety, immunogenicity, and the rate of MRD negativity of LBL-034 monotherapy are further evaluated. The RP2D established from Phase I will be used. The primary endpoint for this phase is the ORR.

Safety results. As of 29 May 2025, no DLT was observed up to a dosage of 1,200 μg/kg, and MTD was not reached.

Figure 27: Safety data observed in the Phase I trial of LBL-034

Category	10μg/kg (N=1)	30μg/kg (N=1)	80μg/kg (N=6)	200μg/kg (N=7)	400μg/kg (N=19)	800μg/kg (N=8)	1200μg/kg (N=3)	Total (N=45)
TEAE	1 (100.0%)	1 (100.0%)	6 (100.0%)	7 (100.0%)	19 (100.0%)	7 (87.5%)	3 (100.0%)	44 (97.8%)
TEAE related to LBL-034	1 (100.0%)	1 (100.0%)	6 (100.0%)	7 (100.0%)	19 (100.0%)	7 (87.5%)	3 (100.0%)	44 (97.8%)
SAE	1 (100.0%)	0 (0.0%)	2 (33.3%)	5 (71.4%)	6 (31.6%)	3 (37.5%)	0 (0.0%)	18 (40.0%)
SAE related to LBL-034	1 (100.0%)	0 (0.0%)	1 (16.7%)	4 (57.1%)	5 (26.3%)	2 (25.0%)	0 (0.0%)	13 (28.9%)
Grade ≥3 TEAE	1 (100.0%)	0 (0.0%)	1 (16.7%)	4 (57.1%)	14 (73.7%)	5 (62.5%)	3 (100.0%)	36 (80.0%)
Grade ≥3 TEAE related to LBL-034	1 (100.0%)	0 (0.0%)	1 (16.7%)	4 (57.1%)	12 (63.2%)	3 (37.5%)	2 (66.7%)	23 (73.3%)
TEAE leading to treatment interruption and related to LBL-034	1 (100.0%)	0 (0.0%)	0 (0.0%)	4 (57.1%)	6 (31.6%)	3 (37.5%)	2 (66.7%)	17 (37.8%)
TEAE leading to permanent discontinuation and related to LBL-034	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (14.3%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (2.2%)
TEAE leading to dose reduction and related to LBL-034	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)

Note: TEAE refers to treatment emergent adverse events; SAE refers to serious adverse event
Source: Company data (as of February 28, 2025)

Source: Company data, CMBIGM
Note: Data as of 28 February 2025.

Figure 28:The most common TEAEs observed in the Phase I trial of LBL-034 vs Talvey

Hematological Toxicity

TEAEs, n (%)	Any Grade		≥Grade 3	
	LBL-034	Talvey[1][2]	LBL-034	Talvey[1][2]
Lymphocyte Count Decreased	**37 (66.1%)**	303 (89.4%)	**28 (50.0%)**	268 (79.1%)
Platelet Count Decreased	**34 (60.7%)**	211 (62.2%)	**10 (17.9%)**	74 (21.8%)
White Blood Cell Decreased	**33 (58.9%)**	246 (72.6%)	**14 (25.0%)**	117 (34.5%)
Neutrophil Count Decreased	**26 (46.4%)**	216 (63.7%)	**14 (25.0%)**	117 (34.5%)
Anemia	**30 (53.6%)**	228 (67.3%)	**9 (16.1%)**	102 (30.1%)

- Majority of TEAEs were observed during the initial phase of treatment, when MM was still uncontrolled.
- Most TEAEs did not compromise treatment continuity or adversely affect the patients' quality of life.

Non-hematological Toxicity

TEAEs, n (%)	Any Grade		≥Grade 3	
	LBL-034	Talvey[1][2]	LBL-034	Talvey[1][2]
CRS	**38 (67.9%)**	257 (75.8%)	**1 (1.8%)**	5 (1.5%)
Nail disorder	**24 (42.9%)**	168 (49.6%)	**0 (0.0%)**	0 (0.0%)
Skin disorder	**23 (41.1%)**	139 (41.0%)	**0 (0.0%)**	1 (0.3%)
Pruritus	**15 (26.8%)**	66 (19.5%)	**0 (0.0%)**	1 (0.3%)
Rash	**10 (17.9%)**	127 (37.5%)	**0 (0.0%)**	12 (3.5%)
Musculo-skeletal pain	**8 (14.3%)**	146 (43.1%)	**2 (3.6%)**	11 (3.2%)
Pain	**3 (5.4%)**	60 (17.7%)	**0 (0.0%)**	6 (1.8%)
Dry mouth	**5 (8.9%)**	114 (33.6%)	**0 (0.0%)**	0 (0.0%)
Dysgeusia	**25 (44.6%)**	238 (70.2%)	**0 (0.0%)**	0 (0.0%)
Weight decreased	**7 (12.5%)**	119 (35.1%)	**0 (0.0%)**	5 (1.5%)
Decreased appetite	**5 (8.9%)**	64 (18.9%)	**0 (0.0%)**	4 (1.2%)
Fatigue	**6 (10.7%)**	124 (36.6%)	**0 (0.0%)**	12 (3.5%)
Headache	**3 (5.4%)**	63 (18.6%)	**0 (0.0%)**	2 (0.6%)

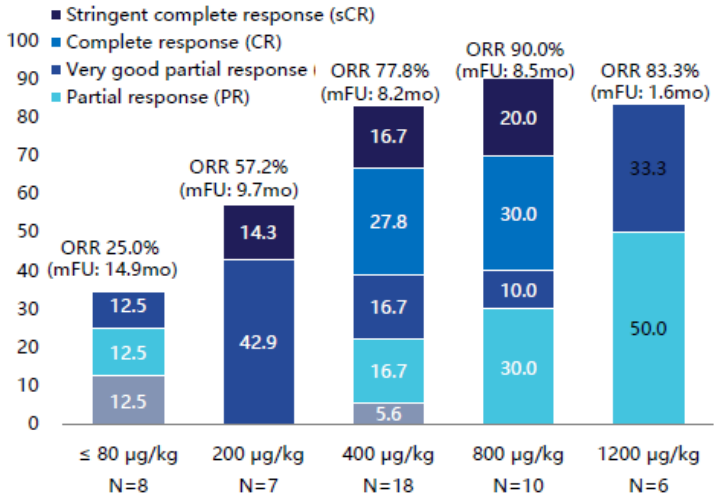
N=56 for LBL-034, N=339 for Talvey

Source: Company data, CMBIGM

Note: data as of 29 May 2025, not head-to-head comparison.

Efficacy results. As of 29 May 2025, an ORR of 82.1% was observed across the 400-800 μg/kg dose levels. Notably, higher doses demonstrated CAR T-like efficacy without posing additional safety concerns. Specifically, in the 400 μg/kg group (n=18), the ORR was 77.8%, with a very good partial response or better (≥VGPR) rate of 61.1% and a complete response or better (≥CR) rate of 44.4%. The 800 μg/kg group (n=10) achieved an ORR of 90.0%, with ≥VGPR and ≥CR rates of 60.0% and 50.0%, respectively. Further, patients with extramedullary disease also exhibited substantial clinical benefit with a favorable safety profile, and the rate of minimal residual disease (MRD) negativity was appreciably higher than that reported with current standard therapies. Additionally, an encouraging trend toward prolonged PFS was observed. The most updated data will be presented at the 2025 ASH Annual Meeting.

Figure 29:The details of responding patients



*6 patients were enrolled in 1,200 μg/kg group; enrollment was completed in late April 2025. With a median follow-up of only 1.6 months, the dataset remains immature

	LBL-034	Talquetamab
CR+sCR	44.4% (8/18) (400 μg/Kg) 50.0% (5/10) (800 μg/Kg)	22% (10/44) (800 μg/kg) s.c. biweekly (NEJM, 2022)
ORR*	82.1% (23/28) (400-800 μg/Kg)	64% (800 μg/kg) (NEJM, 2022)

Source: Company data, CMBIGM

Note: Data as of 29 May 2025.

To start a single-arm registration trial

Subject to clinical results of Phase I, the Company plans to proceed with consultation with the CDE for a single-arm registrational trial, and targets to submit the first BLA in China by the second half of 2026. In October 2024, LBL-034 obtained the ODD from the FDA for the treatment of MM, which currently the Company does not have a clinical development plan to initiate overseas clinical trials of LBL-034. Upon obtaining results from the registrational trial in China, the Company will leverage the data to attract high-quality global partners for further development and commercialization of this asset in the global market.

Leads Biolabs is advancing LBL-034 in combination therapies to progress towards a frontline treatment for MM. Based on data of the ongoing monotherapy Phase I/II trial for LBL-034 in MM, future combination therapy strategies will be determined.

LBL-007 (LAG-3 mAb), promising efficacy proven in NPC

LBL-007 is a fully human IgG4 monoclonal antibody targeting lymphocyte activation gene-3 (LAG3), designed for the treatment of NPC, NSCLC, CRC, ESCC, HNSCC, melanoma and other solid tumors. It ranks among the top tier of LAG3-targeted clinical-stage monoclonal antibodies globally in terms of clinical development (other than the only one marketed LAG3-targeted drug). LBL-007 is the first in its class with proven efficacy in NPC.

LAG3 is an immune checkpoint receptor expressed on activated T-cells, negatively regulating these cells through multiple identified ligands, including MHC-II, LSECtin, Gal-3, and FGL1. As LAG3 expression is tied to antigen presentation, continuous antigen exposure due to chronic infection or tumor-associated antigens can lead to high and sustained expression of LAG3 on T-cells, causing them to become functionally “exhausted” and lose their effector functions. This loss of T-cell function results in diminished immunosurveillance and promotes tumor escape. By binding to LAG3, LBL-007 prevents it from engaging with its ligands, inhibits its signaling pathway, promotes T-cell proliferation and cytokine secretion, and subsequently restores tumor immunosurveillance. The combination of LAG3 inhibitors with PD-1/PD-L1 agents shows powerful synergistic effects in cancer treatment by improving T-cell function to fight tumors. This combination therapy both increases the number of active T-cells and enhances their tumor-fighting ability, while helping overcome PD-1 resistance that limits current cancer treatments.

Market opportunities and competition of LBL-007

The emergence of LAG3 therapies represents a significant milestone in immuno-oncology therapy, marking a new direction in immune checkpoint inhibition. Extensive preclinical studies and ongoing clinical trials have demonstrated the crucial role of LAG3 in T-cell regulation and antitumor immune responses. Despite this advancement, these therapies face challenges, including limited efficacy and the risk of adverse events. These limitations highlight the necessity for ongoing research to enhance their effectiveness and safety profiles. Combining LAG3 inhibitors with other checkpoint inhibitors, such as PD-1 inhibitors, offers a promising approach that potentially leads to more effective treatment regimens. This opens opportunities for combination therapies that can enhance overall treatment efficacy. The combination use of LBL-007 with PD-1 inhibitors exhibits promising antitumor effects and favorable safety across various tumor types in the clinical studies. These impressive response rate and survival benefits position LBL-007 as the first LAG3 antibody to show meaningful efficacy in NPC.

While Opdualag is currently the only marketed LAG3 therapy, its clinical use has been limited to melanoma patients. LBL-007 has emerged as one of the top three LAG3-targeted clinical-stage monoclonal antibodies globally in terms of clinical development stage, and it is being evaluated in clinical trials for one of the largest number of targeted indications in its class.

Figure 30: Clinical-stage LAG3 antibodies globally and certain details of Opdualag

Drug Name	Target	Company	Clinical Stage	Indication	Mono or Combo Therapy in Trial Design	First Posted Date
Fianlimab	LAG3	Regeneron Pharmaceuticals	Phase 3	Melanoma	Combo	2024-02-07
			Phase 2/3	NSCLC	Combo	2023-03-27
			Phase 2	HCC, HNSCC	Combo	2019-04-16
MK-4280	LAG3	Merck Sharp & Dohme	Phase 3	Hodgkin Lymphoma	Combo	2022-08-19
			Phase 2	Cutaneous Squamous Cell Carcinoma, Endometrial Cancer	Combo	2023-09-14
LBL-007	LAG3	Leads Biolabs Co., Ltd	Phase 1/2	NPC and Other Advanced Solid Tumor*	Combo	2021-11-01
BI 754111	LAG3	Boehringer Ingelheim	Phase 2	Advanced or Metastatic Solid Tumor	Combo	2018-10-05
INCAGN02385	LAG3	Incyte Corporation	Phase 2	Endometrial Cancer	Combo	2020-07-09
			Phase 2	HNC	Combo	2022-03-18
			Phase 1/2	Melanoma	Combo	2020-05-01
SHR-1802	LAG3	Hengrui Medicine Co., Ltd.	Phase 2	Advanced Solid Tumor	Combo	2022-01-26
HLX26	LAG3	Henlius Biotech	Phase 2	Advanced NSCLC	Combo	2023-03-28
IBI110	LAG3	Innovent Biologics Co. Ltd.	Phase 2	Advanced or Metastatic ESCC	Combo	2023-10-12
GLS-012	LAG3	Gloria Biosciences Co., Ltd.	Phase 1/2	Advanced NSCLC	Combo	2023-08-07
TSR-033	LAG3	Tesaro, Inc.	Phase 1	Advanced Solid Tumor	Combo	2017-08-16
Sym022	LAG3	Symphogen A/S	Phase 1	Advanced Solid Tumor and Lymphoma	Combo	2017-10-17
TQB2223	LAG3	Chia Tai Tianqing Pharmaceutical Group Co., Ltd.	Phase 1	Advanced HCC	Combo	2024-03-20
IMP761	LAG3	Immutep S.A.S.	Phase 1	Healthy Subjects	Mono	2024-10-15

Drug Name	Brand Name	Target	Company	Indications	Regimen	Approval Date	Annual Treatment Cost in the US
Nivolumab + Relatlimab	OPDUALAG®	LAG3	BMS	Unresectable or Metastatic Melanoma	Combo	2022-03-18	Annual treatment cost is around US$370 thousand

Source: Company data, ClinicalTrials.gov, CMBIGM. Note: as of 28 May 2025; * The trial has been substantially completed in September 2024 and are in the process of finalizing the clinical study report.

NPC, a type of head and neck cancer, predominantly affects the epithelial cells lining the inner surface of the nasopharynx, located behind the nasal cavity. Currently, gemcitabine and cisplatin are the standard first-line treatments for recurrent or metastatic NPC. However, the outcomes remain suboptimal, with a median PFS of eight to nine months and a mOS of less than two years with chemotherapy alone. Compared to chemotherapy alone, patients who received immunotherapy in combination with chemotherapy demonstrated significantly improved ORR, PFS, and OS. However, long-term chemotherapy use leads to acute toxicities, grade 3 and above, such as acute mucositis and torrential bleeding.

Furthermore, unlike most solid tumors where LAG3 inhibitors have demonstrated only modest clinical activity since LAG3 expression is often low and the immunosuppressive network diffuse, NPC is almost always associated with Epstein-Barr virus (EBV) infection, which drives high co-expression of LAG3 and PD-L1 on both tumor cells and tumor-infiltrating lymphocytes. This dual-high checkpoint profile creates a clear rationale for combined blockade of LAG3 and PD-1, since a large fraction of NPC-infiltrating T cells co-express both receptors. Moreover, EBV-positive NPC patients typically achieve only 20-30% response rates with anti-PD-1 monotherapy and rapidly develop resistance. By pairing LAG3 and PD-1 inhibition, potentially alongside chemotherapy, radiotherapy or EBV-targeted therapies, developers can exploit NPC's unique tumor microenvironment and pursue a mechanism-driven, differentiated strategy with genuine promise in high-incidence regions worldwide.

The combination of LBL-007 with tislelizumab and chemotherapy has demonstrated more favorable ORR and 9-month PFS rate in the clinical trials compared to the combination of tislelizumab and chemotherapy regimen, representing a more effective treatment option than the current standard of care for NPC. Leads Biolabs' LBL-007 also revealed potential in treating other solid tumors, including NSCLC, CRC, ESCC, and HNSCC.

Competitive advantages especially in combination with PD-1 inhibitors

Promising efficacy both as a monotherapy and in strong synergistic effects with PD-1 inhibitors

In a Phase II trial, LBL-007 in combination with tislelizumab and chemotherapy achieved an ORR of 83.3% for first line NPC. The 9-month PFS rate has been reported at an impressive 75.1%, while more than half of patients remain on treatment to date, with median duration of response (mDOR) and median progression-free survival (mPFS) still immature. In comparison, the ORR and median PFS of the combination of tislelizumab and chemotherapy regimen is about 69.5% and 9.2 months, respectively, in patients with 1L NPC, according to the publicly reported clinical data from Rationale-309 (Phase III clinical trial for tislelizumab combined with gemcitabine and cisplatin in 1L RM-NPC). Additionally, the combination therapy has shown effectiveness in patients who do not respond to PD-1 monotherapy.

Favorable safety profile with low risk of immunogenicity as a fully human monoclonal antibody

LBL-007, as a fully human IgG4 monoclonal antibody, exhibits a low risk of immunogenicity and has demonstrated a favorable safety profile validated by preliminary clinical results. In the completed Phase Ia trial, LBL-007 was well-tolerated with manageable safety profile, and no DLTs were observed. In the Phase Ib/II clinical trial of LBL-007 combined with toripalimab, no DLT was observed, and the MTD was not reached up to 400 mg. Furthermore, in the ongoing Phase Ib/II clinical trials combining LBL-007 with tislelizumab and/or chemotherapy, no DLT was observed, and the MTD was not reached up to 600 mg.

Promising clinical trial results in the treatment of NPC

LBL-007 is being evaluated in the clinical trials in combination with anti-PD-1 agents and/or chemotherapy mainly for the treatment of NPC.

Phase I/II clinical trial of LBL-034 monotherapy

Trial design. This is a single-arm, open-label and dose-escalation Phase Ia study to evaluate the safety, tolerability, adverse events, ORR, PK characteristic and immunogenicity of LBL-007 monotherapy in patients with advanced solid tumors. The patients were assigned into six cohorts, receiving LBL-007 at 0.05 mg/kg to 10 mg/kg Q2W. The primary endpoints are tolerability, MTD and adverse events.

Efficacy results. Leads Biolabs has completed this clinical trial in June 2022, with a total of 22 patients enrolled. Among the 18 evaluable patients, one patient achieved PR and four patients achieved SD as of 13 June 2022. These results highlight the potential therapeutic benefit and stability provided by the treatment.

Safety results. LBL-007 monotherapy demonstrated a favorable safety profile, with patients tolerating the treatment well and managing safety concerns effectively. Notably, no DLTs were observed as of 13 June 2022.

Phase Ib/II clinical trials for LBL-007 in combination with tislelizumab and/or chemo in malignant tumors

Trial status. Leads Biolabs has initiated this trial in September 2022 with 98 patients enrolled. As of 13 January 2025, 98 patients with relapsed and refractory advanced solid tumor were enrolled into Phase Ib (n=21) and Phase II (n=77), and the Company completed the Phase Ib cohort of this trial.

Efficacy results. As of 13 January 2025, among 21 patients from Phase Ib who received LBL-007 300mg or 600mg + Tislelizumab 200mg, five patients experienced PRs representing a 23.8% ORR. mPFS was

4.4 months. For 35 recurrent advanced or metastatic NPC patients allocated in part D1 of Phase II, two PR were observed from nine LBL-007 + tislelizumab + docetaxel treated patients, the ORR was 22.2%, comparing with 12.5% in Docetaxel alone group. In 42 previously untreated NPC patients, LBL-007 + Tislelizumab + Gemcitabine + platinum was administrated. ORR was 83.3% while.

In Part D1 of the Phase II trial, LBL-007 was involved in combination with tislelizumab and/or docetaxel for the second-line treatment of NPC following the failure of ICI (n=35). This cohort demonstrated encouraging antitumor signals in NPC patients.

In Part D2 of the Phase II trial, LBL-007 was tested in combination with tislelizumab and GP for the first-line treatment of NPC (n=42). Among the 42 evaluable patients, an ORR of 83.3% (35/42) and DCR of 97.6% (41/42) were observed with mPFS of 15 months, as of 13 January 2025. In comparison, the ORR and median PFS of the combination of tislelizumab and chemotherapy regimen was about 69.5% and 9.2 months, respectively, in patients with recurrent/metastatic NPC, according to the publicly reported clinical data.

Safety results. As of 13 January 2025, there was no DLT, with the MTD of LBL-007 not reached. The safety profile has found to be manageable, with no new safety concerns emerging during this phase. Notably, the most common adverse event associated with the chemotherapy component of the treatment is bone marrow suppression, which was commonly seen in chemotherapy.

Continue the clinical development plan in NPC and melanoma

Leads Biolabs is strategically prioritizing combination therapies with PD-1 inhibitors for LBL-007. The Company has completed patient enrollment for the Phase Ib/II clinical trial for its combination with tislelizumab and/or chemotherapy in advanced NPC and other solid tumors in China in January 2024. The Company remains confident to its ongoing clinical programs of LBL-007 for the treatment of advanced NPC, considering the favorable efficacy and safety profiles. Leads Biolabs also plans to further investigate the potential of LBL-007 in melanoma.

Leads Biolabs entered into a license and collaboration agreement with BeOne Medicines in December 2021 for an exclusive license to develop, manufacture and commercialize LBL-007 outside Greater China. BeOne had then been conducting various global trials to evaluate LBL-007 in combination with tislelizumab and standard of care in NSCLC, CRC, HNSCC and ESCC. The BeOne Agreement was later terminated on 18 May 2025 as specified in the termination notice provided by BeOne. Following this termination, the Company regained full, global rights to develop, manufacture and commercialize LBL-007.

Selected pre-clinical TCE pipeline for tumors and autoimmune diseases

LBL-051 (CD19/BCMA/CD3)

LBL-051 is a CD19/BCMA/CD3 targeting tri-specific antibody, designed for the treatment of B-cell and autoantibody-driven autoimmune diseases, including systemic lupus erythematosus (SLE), generalized myasthenia gravis (gMG), and multiple sclerosis (MS). It is also a therapy with the potential to treat relapsed and refractory multiple myeloma.

CD19 is a selective surface marker expressed on the majority of B cells from the early stages of their development in the bone marrow through to their maturation into plasma cells. The B-cell maturation antigen (BCMA) is highly expressed on plasmablasts and plasma cells and plays a vital role in the regulation of B-cell proliferation, survival, and differentiation. Patients with autoimmune diseases produce autoantibodies against self-components such as DNA, ribosomes, and certain proteins. Since B cells are pivotal in the production of these autoantibodies, targeting CD19 on B cells has emerged as a promising strategy for treatment. This approach aims to eliminate B cells that are producing pathogenic autoantibodies, thereby reducing their levels and mitigating immune-mediated damage.

LBL-051 is a CD19/BCMA/CD3 targeting tri-specific T cell engaging antibody, created with the aim of achieving a –B cell reset in autoimmune diseases. Each target binding domain — CD19, BCMA, and CD3 — has been engineered with the intent of enhancing safety while optimizing efficacy by finely tuning the relative potency of each domain. By targeting both CD19 and BCMA, LBL-051 has the potential to deliver stronger and more durable responses by depleting a broader range of pathological B-cell populations across a wide spectrum of antibody-mediated autoimmune diseases.

Leads Biolabs expects to file IND applications with the FDA and NMPA in the first half of 2026.

On 5 November 2024, the Company entered into a collaboration, exclusive option and license agreement with Oblenio Bio, Inc., a U.S. company newly formed by Aditum Bio, for the global development and commercialization of LBL-051. Under the Agreement, Leads Biolabs is eligible to receive a one-time, non-refundable upfront payment of US$15.0 mn and up to US$20.0 mn in near-term payments. In addition, the Company is entitled to future milestone payments of up to US$579 mn upon the achievement of clinical development, regulatory approval, and commercial milestones. Oblenio will also be required to pay mid-single-digit percentage royalties on aggregate annual net sales of the licensed products worldwide. As a part of the consideration for the exercise of the Option, NewCo will also issue certain preferred shares to Lead Biolabs, which represent ten percent of its outstanding share capital on a fully-diluted basis as of the date of issuance.

LBL-043 LILRB4/CD3

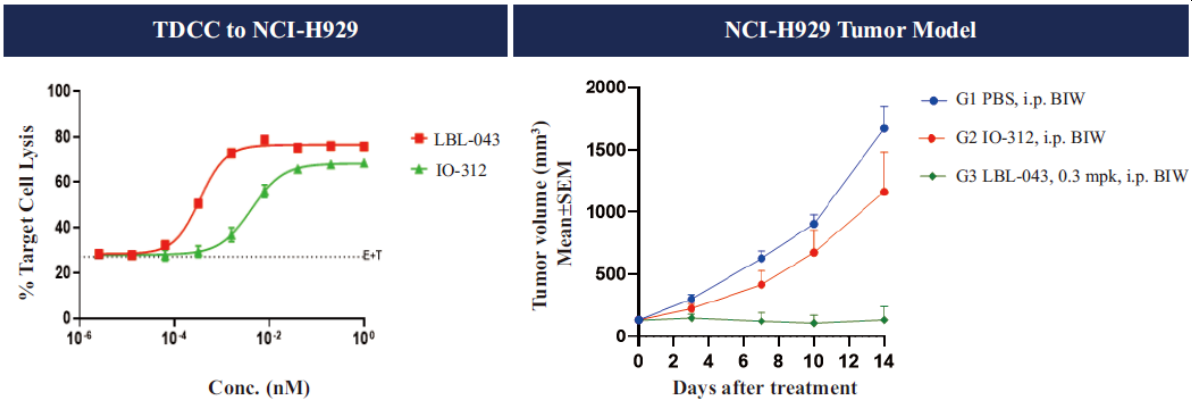
LBL-043 is a bispecific antibody targeting both leukocyte immunoglobulin-like receptor B4 (LILRB4) and CD3 for the treatment of AML and MM. LBL-043 was developed using the Company's proprietary LeadsBody T-cell Engager platform with 2:1 format. There are currently no approved or clinical-stage bispecific antibodies targeting both LILRB4 and CD3 globally.

LILRB4 is an immune checkpoint inhibitory receptor that is overexpressed on French-American-British (FAB) M4 and M5 AML cells but not expressed on normal HSCs and progenitor cells. LILRB4 supports tumor cell infiltration into tissues and suppresses T cell activity in AML cells. The level of LILRB4 expression is inversely correlated with the OS of patients diagnosed with M4 and M5 AML, highlighting its potential as a therapeutic target. Developed through the proprietary LeadsBody platform, LBL-043 is a therapeutic agent that exploits this target specificity. LBL-043 is designed with a unique 2:1 format, incorporating two VHH arms that bind to LILRB4 with high affinity, and one scFv arm that targets CD3 with precisely tuned lower affinity. This design ensures potent activation of T cells via CD3 engagement,

while primarily targeting the cancer cells expressing LILRB4, thus offering a highly differentiated approach to treating AML.

The *in vitro* and *in vivo* studies have demonstrated that LBL-043 exhibits strong antitumor effects. LILRB4 is also found to be expressed on MM tumor cells, and it demonstrated more potent TDCC and *in vivo* antitumor activity on LILRB4+ MM tumor cell lines compared to the benchmark IO-312.

Figure 31: Selected data of LBL-043



Source: Company data, CMBIGM

These promising outcomes support LBL-043's potential as an effective therapeutic agent in targeting cancer cells. These studies validate the Company's approach and provide a solid foundation for the further development of LBL-043 in clinical settings. Leads Biolabs expects to file IND applications with the FDA and NMPA in the first half of 2026.

LBL-054-TCE (CDH17/CD3)

LBL-054-TCE is a bispecific T-cell engager antibody targeting CDH17, a protein overexpressed in gastrointestinal cancers, making it a promising candidate for the treatment of CDH17-positive gastrointestinal tumors. Leveraging the proprietary LeadsBody T-cell engager platform, LBL-054-TCE is engineered with high-affinity binding arms for CDH17 and a finely tuned CD3 arm to maximize antitumor efficacy while minimizing potential off-target toxicity. This bispecific antibody facilitates the selective recruitment and activation of T cells to specifically kill CDH17-positive tumor cells.

LBL-054-TCE has demonstrated significant therapeutic potential in preclinical studies. Its binding affinity to the membrane-proximal region of CDH17 has been shown to be highly specific, with no cross-reactivity to other cadherin family proteins. In vitro cytotoxicity assays confirmed that LBL-054-TCE mediates tumor cell killing in a CDH17 expression-dependent manner while sparing CDH17-negative cells. Furthermore, preclinical investigations revealed that the bispecific antibody induces moderate cytokine release and T-cell activation, ensuring a balanced approach to efficacy and safety. In PBMC-humanized mouse models bearing gastrointestinal tumor xenografts, LBL-054-TCE exhibited robust antitumor activity.

The Company expects to file an IND application for LBL-054-TCE in the first half of 2027.

LBL-054-ADC (CDH17 ADC)

LBL-054-ADC is an ADC targeting CDH17, a calcium-dependent cell adhesion molecule that is overexpressed and redistributed on the surface of 50% to 90% of gastrointestinal tumors, including

gastric and colorectal cancers. This unique overexpression and surface localization in cancer cells, while being hidden in normal intestinal tissue, make CDH17 an ideal target for ADC-based therapies.

LBL-054-ADC is empowered by the Company's proprietary linker-payload platform, featuring a humanized IgG1 monoclonal antibody with high specificity for CDH17. The antibody has been engineered to remove Fc functionality, reducing blood toxicity, and is further optimized to achieve a drug-to-antibody ratio of six, striking a balance between efficacy and safety. The payload is a clinically validated, highly potent TOP1i optimized for high activity, permeability, and resistance to drug efflux mechanisms. This payload enables a strong bystander effect, enhancing LBL-054-ADC's ability to target tumors with heterogeneous CDH17 expression, as well as resistant cell populations. The linker used in LBL-054 contains a cleavable peptide, a hydrophilic spacer, and a stable conjugation moiety that prevents reversible Michael addition reactions. This design ensures excellent physicochemical properties, high plasma stability, and rapid payload release at tumor sites.

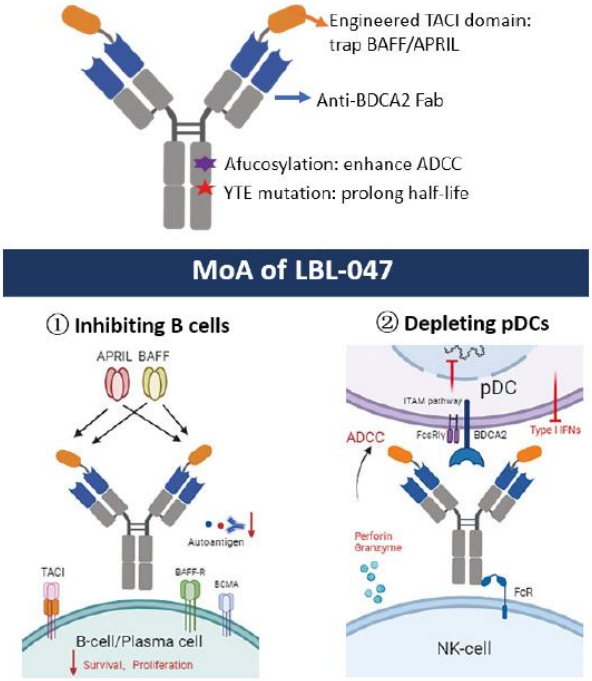
Preclinical studies have demonstrated that LBL-054-ADC has robust binding affinity to CDH17 and undergoes rapid internalization into tumor cells. Killing assays confirmed that LBL-054-ADC is highly potent against CDH17-positive cancer cells and exhibits a superior bystander effect compared to alternative conjugates like LBL-054-Dxd. In xenograft models, a single dose of LBL-054 showed significant tumor regression, demonstrating stronger anti-tumor efficacy and better pharmacokinetics than comparator ADCs. Furthermore, LBL-054-ADC exhibited high stability in plasma and excellent tolerability, indicating its potential for clinical development.

Leads Biolabs expects to file an IND application for LBL-054-ADC in the second half of 2026.

LBL-047 (anti-BDCA2/TACI bispecific fusion protein)

LBL-047 is a bispecific fusion protein composed of a humanized anti-BDCA2 antibody and an engineered TACI ectodomain. It targets both BAFF/APRIL and BDCA2, designed to simultaneously inhibit the activity of plasmacytoid dendritic cells (pDCs) and the differentiation and activation of B cells for the treatment of autoimmune diseases, including systemic lupus erythematosus (SLE), cutaneous lupus erythematosus (CLE), IgA nephropathy (IgAN) and scleroderma. The glycosylation of LBL-047 is modified to enhance ADCC effects, and the Fc region is engineered to achieve an extended half-life. There are currently no approved or clinical-stage fusion proteins targeting both BDCA2 and TACI globally.

Figure 32: Molecular structure and the mechanism of action of LBL-047



Source: Company data, CMBIGM

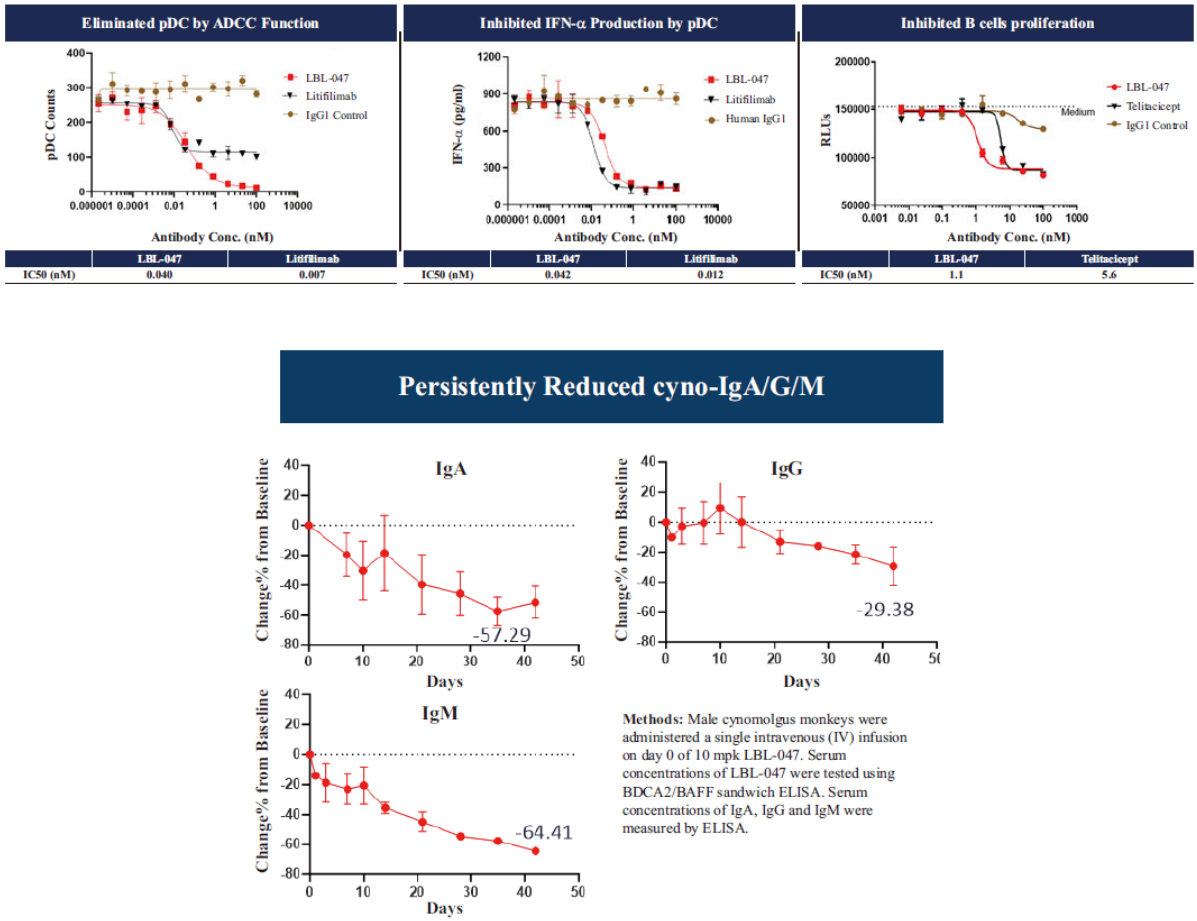
B cells and pDCs play crucial and synergistic roles in the pathogenesis of various autoimmune diseases. BAFF (B-cell activating factor) and APRIL (a proliferation-inducing ligand) are key cytokines that promote the survival, maturation, and function of B cells and plasma cells. TACI is the natural high-affinity receptor for BAFF and APRIL. An engineered TACI domain can be used to trap BAFF and APRIL, thereby inhibiting their signaling. This inhibition presents a potential therapeutic strategy for treating B cell-related autoimmune diseases.

BDCA2 is uniquely expressed on pDCs, serving a pivotal role in their immune function. Upon ligand binding, BDCA2 activates the ITAM pathway through SRC family protein tyrosine kinases (PTKs), leading to the activation of SYK, BLNK, and BCAP. This signaling cascade culminates in the production of type I interferons (IFNα, IFNβ) and pro-inflammatory cytokines (IL-6, TNF) via the TLR pathway. The unique expression and intricate signaling mechanisms of BDCA2 on pDCs provide critical insights into their role in immune responses, highlighting potential therapeutic targets for a range of diseases. Notably, BDCA2 has demonstrated promising efficacy, as evidenced by Biogen's monoclonal antibody litifilimab, which is currently in Phase III development. The mechanism of action of LBL-047 involves targeting pDCs to reduce IFN-α production and blocking B cell activation by competitively binding to APRIL and BAFF with its engineered TACI trap fusion component. This dual approach suppresses aberrant immune responses in autoimmune diseases.

Comprehensive in vitro and in vivo studies have demonstrated the promising efficacy of LBL-047. In vitro assessments revealed that LBL-047 could completely eliminate pDCs, showing a more potent elimination capacity than litifilimab. This superior efficacy was also observed in the huHSC-NCG mouse model, an in vivo system, where LBL-047 again outperformed litifilimab in eliminating pDCs. Beyond its impact on pDCs and IFN-α, LBL-047 has demonstrated superior inhibition of B cell proliferation compared to telitacicept, both in vitro and in a delayed-type hypersensitivity mouse model. Furthermore, in an EAE mouse model (a multiple sclerosis model), LBL-047 showed greater efficacy in attenuating clinical symptoms and reducing B cells and plasma cells. Preliminary pharmacokinetics studies in cynomolgus monkeys indicated an excellent PK profile, with a marked reduction in circulating IgA, IgG,

and IgM. These findings underscore LBL-047's potential as a highly effective therapeutic option in conditions where modulation of B cell and pDCs function is crucial.

Figure 33: Selected data of LBL-047



Source: Company data, CMBIGM

The Company expects to file IND applications with the FDA and NMPA in the second half of 2025.

Financial Analysis

We expect Leads Biolabs to begin generating product sales revenue in 2027E, primarily driven by LBL-024 (PD-L1/4-1BB) and LBL-034 (GPRC5D/CD3). We expect these two assets to account for most of the Company's sales revenue in China in the long term.

Figure 34: Revenue forecasts

Revenue (RMB mn)	2023	2024	2025E	2026E	2027E
Sales of goods in China	**0**	**0**	**0**	**0**	**151**
LBL-024 (PD-L1/4-1BB)	0	0	0	0	64
LBL-034 (GPRC5D/CD3)	0	0	0	0	87
LBL-033 (MUC16/CD3)	0	0	0	0	0
LBL-007 (LAG-3 mAb)	0	0	0	0	0
Other products	0	0	0	0	0
Licensing revenue & service income	**9**	**0**	**251**	**0**	**208**
LBL-051 (CD19/BCMA/CD3) - upfront & milestone from Oblenio	0	0	251	0	104
LBL-051 (CD19/BCMA/CD3) - royalties from Oblenio	0	0	0	0	0
LBL-007 (LAG-3 mAb) - upfront & milestone from BeOne	9	0	0	0	0
Others	0	0	0	0	104
Total	**9**	**0**	**251**	**0**	**359**

Source: Company data, CMBIGM estimates

Leads Biolabs recorded net losses of RMB362/301mn in FY23/24A. We expect the Company to book attributable net loss of RMB176mn/ 415mn/ 319mn in FY25E /26E/ 27E.

Figure 35: P&L forecasts

YE Dec 31 (RMB mn)	2023	2024	2025E	2026E	2027E
Revenue	**9**	**0**	**251**	**0**	**359**
YoY					
Cost of sales	(3)	0	0	0	(27)
% of revenue					*8%*
Gross profit	**6**	**0**	**251**	**0**	**332**
GPM					*92%*
R&D expenses	(231)	(186)	(300)	(360)	(431)
% of revenue					*120%*
Administrative expenses	(38)	(88)	(150)	(100)	(126)
% of revenue					*35%*
Selling and distribution expenses	0	0	0	0	(121)
% of revenue					*34%*
Profit/(loss) before tax	**(362)**	**(301)**	**(176)**	**(415)**	**(319)**
Income tax benefit (expense)	0	0	0	0	0
Non-controlling interests	0	0	0	0	0
Attributable net profit/(loss)	**(362)**	**(301)**	**(176)**	**(415)**	**(319)**

Source: Company data, CMBIGM estimates

Valuation

Initiate at BUY with TP of HK$80.27

We expect Leads Biolabs to start generating product sales revenue in 2027E. We derive our target price of HK$80.27 based on a DCF model (WACC: 9.06%, terminal growth rate 4.0%).

Figure 36: Risk-adjusted DCF valuation

DCF Valuation (RMB mn)	2025E	2026E	2027E	2028E	2029E	2030E	2031E	2032E	2033E	2034E	2035E	2036E	2037E	2038E	2039E	2040E
EBIT	**-166**	**-404**	**-292**	**-347**	**-267**	**-6**	**457**	**954**	**1,548**	**2,078**	**2,066**	**2,110**	**2,148**	**2,172**	**2,211**	**2,270**
Tax rate	*0%*	*0%*	*0%*	*0%*	*0%*	*0%*	*15%*	*15%*	*15%*	*15%*	*15%*	*15%*	*15%*	*15%*	*15%*	*15%*
EBIT*(1-tax rate)	-166	-404	-292	-347	-267	-6	388	811	1,316	1,766	1,756	1,794	1,826	1,846	1,880	1,930
+ D&A	16	17	22	38	39	40	41	42	43	43	44	45	45	45	46	46
- Change in working capital	-53	0	-51	-71	-69	-107	-296	-258	-274	-166	-37	43	56	75	73	70
- Capex	-20	-20	-200	-200	-50	-50	-50	-50	-50	-50	-50	-50	-50	-50	-50	-50
FCFF	**-223**	**-407**	**-521**	**-579**	**-347**	**-123**	**84**	**546**	**1,035**	**1,594**	**1,714**	**1,831**	**1,877**	**1,917**	**1,948**	**1,996**
Terminal value																**41,000**

Present value (RMB mn)	13,549
Net debt (RMB mn)	-1,138
Equity value (RMB mn)	**14,688**
Equity value (HK$ mn)	**15,965**
No. of shares (mn)	199
DCF per share (HK$)	**80.27**
Terminal growth rate	**4.0%**
WACC	**9.06%**
Cost of equity	12.0%
Cost of debt	2.6%
Equity beta	0.9
Risk free rate	3.0%
Market risk premium	10.0%
Target debt to asset ratio	30.0%
Effective corporate tax rate	15.0%

Source: CMBIGM estimates

Figure 37: Sensitivity analysis (HK$)

		WACC				
		8.06%	**8.56%**	**9.06%**	**9.56%**	**10.06%**
	5.0%	135.43	112.12	**94.70**	81.24	70.56
	4.5%	119.82	101.13	86.69	75.24	65.96
Terminal growth rate	**4.0%**	108.04	92.55	**80.27**	70.32	62.12
	3.5%	98.85	85.67	75.00	66.21	58.87
	3.0%	91.47	80.02	**70.60**	62.73	56.08

Source: Company data, CMBIGM estimates

Investment Risks

Risks related to research and development of drug candidates
Leads Biolabs depends substantially on the success of its drug candidates. If it is unable to successfully complete clinical development, obtain regulatory approvals, or achieve commercialization for its drug candidates, or if it experiences significant delays or cost overruns in doing any of the foregoing, its business and prospects could be materially and adversely affected.

Leads Biolabs faces intense competition and rapid technological change, and there is a possibility that its competitors may develop therapies that are similar, more advanced, or more effective than its own, which may adversely affect its financial condition and ability to successfully commercialize drug candidates.

Risks of continuing to incur net losses
Leads Biolabs is a clinical-stage biopharmaceutical company with a limited operating history, which may make it difficult to evaluate its current business and predict its future performance. The Company has incurred net losses since its inception and anticipates that it may continue to incur net losses in the foreseeable future, potentially never achieving or maintaining profitability.

Appendix: Company Profile

Figure 38: Directors and management profile

Name	Age	Positions	Date of joining the Group
Dr. Kang Xiaoqiang	64	Co-founder, Chairman of Board, Executive Director, CEO and general manager	November 2012
Dr. Lai Shoupeng	80	Co-founder, Executive Director, Chief Strategic Officer and Executive Vice President	November 2012
Mr. Zuo Honggang	48	Executive Director, Chief Financial Officer and Secretary of the Board	January 2024
Dr. Cai Shengli	55	Chief Medical Officer	July 2022
Dr. Ling Hong	66	Senior Vice President and Chief Scientific Officer	July 2020

Source: Company data

Figure 39: Employee structure

Function	# of staff	% of total staff
Drug discovery and preclinical development	44	23.4%
Medical and clinical development	53	28.2%
CMC and manufacturing	59	31.4%
Business Development	4	2.1%
General and Administrative	28	14.9%
Total	**188**	**100%**

Source: Company data (as of Feb 2025)

Financial Summary

INCOME STATEMENT	2022A	2023A	2024A	2025E	2026E	2027E
YE 31 Dec (RMB mn)						
Revenue	**0**	**9**	**0**	**251**	**0**	**359**
Cost of goods sold	0	(3)	0	0	0	(27)
Gross profit	**0**	**6**	**0**	**251**	**0**	**332**
Selling expense	0	0	0	0	0	(121)
Admin expense	(24)	(38)	(88)	(150)	(100)	(126)
R&D expense	(185)	(231)	(186)	(300)	(360)	(431)
Gain/loss on financial assets at FVTPL	23	6	2	0	0	0
Interest expense	(0)	(1)	(6)	(10)	(10)	(26)
Other income/expense	0	0	(0)	0	0	0
Others	(104)	(118)	(42)	0	0	0
Pre-tax profit	**(281)**	**(362)**	**(301)**	**(176)**	**(415)**	**(319)**
Income tax	0	0	0	0	0	0
Minority interest	0	0	0	0	0	0
Adjusted net profit	**(281)**	**(362)**	**(301)**	**(176)**	**(415)**	**(319)**

BALANCE SHEET	2022A	2023A	2024A	2025E	2026E	2027E
YE 31 Dec (RMB mn)						
Current assets	**539**	**367**	**596**	**1,617**	**1,200**	**1,510**
Cash & equivalents	253	248	373	1,393	976	1,228
Restricted cash	0	0	0	0	0	0
Receivables	0	0	0	0	0	33
Inventories	0	0	0	0	0	25
Prepayment	44	19	58	58	58	58
Financial assets at FVTPL	241	100	166	166	166	166
Other current assets	2	0	0	0	0	0
Non-current assets	**85**	**80**	**73**	**77**	**80**	**258**
PP&E	57	54	36	40	43	221
Right-of-use assets	9	7	11	11	11	11
Intangibles	0	0	0	0	0	0
Other non-current assets	19	19	26	26	26	26
Total assets	**624**	**447**	**669**	**1,694**	**1,279**	**1,768**
Current liabilities	**1,226**	**1,395**	**398**	**345**	**345**	**1,153**
Short-term borrowings	0	61	255	255	255	1,055
Account payables	28	26	53	0	0	7
Other current liabilities	1,156	1,304	0	0	0	0
Lease liabilities	4	4	6	6	6	6
Contract liabilities	38	0	84	84	84	84
Non-current liabilities	**4**	**2**	**6**	**6**	**6**	**6**
Other non-current liabilities	4	2	6	6	6	6
Total liabilities	**1,231**	**1,396**	**404**	**351**	**351**	**1,158**
Share capital	17	17	157	157	157	157
Retained earnings	0	0	0	(176)	(591)	(910)
Other reserves	(623)	(966)	109	1,363	1,363	1,363
Total shareholders equity	**(606)**	**(949)**	**266**	**1,344**	**929**	**610**
Minority interest	0	0	0	0	0	0
Total equity and liabilities	**624**	**447**	**669**	**1,694**	**1,279**	**1,768**

CASH FLOW	2022A	2023A	2024A	2025E	2026E	2027E
YE 31 Dec (RMB mn)						
Operating						
Profit before taxation	**(281)**	**(362)**	**(301)**	**(176)**	**(415)**	**(319)**
Depreciation & amortization	14	20	20	16	17	22
Tax paid	0	0	0	0	0	0
Change in working capital	138	18	70	(53)	0	(51)
Others	85	132	92	10	10	26
Net cash from operations	**(44)**	**(193)**	**(119)**	**(203)**	**(387)**	**(321)**
Investing						
Capital expenditure	(29)	(12)	(3)	(20)	(20)	(200)
Net proceeds from disposal of short-term investments	83	147	(64)	0	0	0
Others	0	0	0	0	0	0
Net cash from investing	**54**	**135**	**(67)**	**(20)**	**(20)**	**(200)**
Financing						
Dividend paid	0	0	0	0	0	0
Net borrowings	0	60	189	(10)	(10)	774
Proceeds from share issues	0	0	131	1,254	0	0
Others	(3)	(10)	(10)	0	0	0
Net cash from financing	**(3)**	**49**	**309**	**1,244**	**(10)**	**774**
Net change in cash						
Cash at the beginning of the year	239	253	248	373	1,393	976
Exchange difference	6	3	2	0	0	0
Cash at the end of the year	**253**	**248**	**373**	**1,393**	**976**	**1,228**

GROWTH	2022A	2023A	2024A	2025E	2026E	2027E
YE 31 Dec						

PROFITABILITY	2022A	2023A	2024A	2025E	2026E	2027E
YE 31 Dec						
Gross profit margin	na	64.1%	na	100.0%	na	92.4%
Adj. net profit margin	na	(4,086.3%)	na	(70.0%)	na	(88.8%)

GEARING/LIQUIDITY/ACTIVITIES	2022A	2023A	2024A	2025E	2026E	2027E
YE 31 Dec						
Current ratio (x)	0.4	0.3	1.5	4.7	3.5	1.3

VALUATION	2022A	2023A	2024A	2025E	2026E	2027E
YE 31 Dec						
P/E	na	na	na	ns	ns	ns
P/B	na	na	na	8.6	12.5	19.0

Source: Company data, CMBIGM estimates. Note: The calculation of net cash includes financial assets.

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