China Healthcare

ASCO 2026 review: Chinese biopharma showcases historic milestones and global competitiveness

OUTPERFORM (Maintain)

China Healthcare Sector

Jill WU, CFA
(852) 3900 0842
jillwu@cmbi.com.hk

Andy WANG
(852) 3657 6288
andywang@cmbi.com.hk

Cathy WANG
(852) 3916 1729
cathywang@cmbi.com.hk

At the 2026 ASCO Annual Meeting, China's innovative drug sector continued to demonstrate robust clinical momentum, delivering 13 highly anticipated studies during the Late-Breaking Abstract (LBA) session. A historic highlight of the conference was Akeso's HARMONi-6 trial, which was featured in the prestigious Plenary Session—marking the first time a China-originated innovative drug has achieved this top-tier recognition in ASCO's history. Broadly, the clinical datasets presented underscore the accelerating global competitiveness and R&D maturation of Chinese biotech firms. In this report, we provide our analysis and key takeaways regarding the pivotal clinical readouts from Akeso, Kelun-Biotech, Innovent, BeOne Medicines, and 3SBio. Ultimately, we view these compelling datasets as strong catalysts capable of driving a broad valuation re-rating across the Chinese innovative drug sector.

- **Akeso: Compelling HARMONi-6 profile even with caveats.** The China HARMONi-6 trial evaluating ivonescimab plus chemotherapy in 1L sq-NSCLC marks a historic milestone, delivering an impressive OS HR of 0.66 (p=0.0017) alongside a previously reported PFS HR of 0.60 (p<0.0001). This definitive OS advantage effectively resolves lingering investor doubts regarding the translation of PFS benefits into survival gains. However, caveats remain regarding data maturity – with the 21.4-month median follow-up currently trailing the median OS of both arms – and muted efficacy in elderly patients (≥65 years, HR=0.93, 95% CI 0.64-1.36). Despite these nuances, ivonescimab's overall clinical profile remains highly compelling. Looking ahead, the global HARMONi-3 readout (final PFS and interim OS) expected in 2H26 will serve as a critical catalyst, validating whether domestic efficacy results can be successfully replicated in Western populations.
- **Kelun-Biotech: Validating ADC+IO synergy in 1L NSCLC.** The Phase 3 OptiTROP-Lung05 marks a historic milestone by validating the sac-TMT plus pembrolizumab as a potent first-line therapy for PD-L1≥1% NSCLC. The regimen demonstrated exceptional efficacy, delivering a PFS HR of 0.35 and an estimated median PFS of 16.7 months versus pembrolizumab monotherapy. This sac-TMT plus pembrolizumab combination regimen compares favorably against ivonescimab monotherapy (HARMONi-2), which yielded a PFS HR of 0.51 and an 11.1-month mPFS vs pembrolizumab. Meanwhile, besides direct competition with the PD-1/VEGF bsAb, we also see synergy of sac-TMT in combination with PD-1/VEGF bsAb. The safety profile of sac-TMT + pembrolizumab was generally manageable with 6.3% Grade ≥3 stomatitis and 9.1% drug-related discontinuation rate. Looking ahead, we see significant strategic upside as Kelun-Biotech plans to evaluate sac-TMT combined with its in-licensed PD-1/VEGF bsAb, CR-001, particularly in 1L nsq-NSCLC. Concurrently, we anticipate MSD will explore combining sac-TMT with its PD-1/VEGF asset, MK-2010.
- **Innovent: A major step in dose selection of IBI363 in 1L NSCLC**. Innovent has achieved a key clinical milestone by selecting the 3-1.5 mg/kg step-down dosing regimen for IBI363 in first-line NSCLC. This cohort (N=22) demonstrated an optimal risk-reward profile, delivering a highly competitive confirmed ORR of 81.8% and a manageable 65.2% rate of Grade ≥3 TEAEs, comparing favorably to the standard of care. Consequently, Innovent is advancing a head-to-head Phase 1 trial evaluating IBI363 plus chemotherapy against pembrolizumab plus chemotherapy in 1L NSCLC (n=190). Furthermore, IBI363 monotherapy continues to exhibit robust efficacy in IO-resistant settings. A Phase 3 MRCT trial is currently ongoing for sq-NSCLC. Meanwhile, promising mPFS and mOS data in the nsq-NSCLC cohort were also observed, particularly among smokers, which

outperforms SoC docetaxel. Innovent is also planning a Phase 3 study of IBI363 in IO-resistant nsq-NSCLC.

- **BeOne Medicines: Solid tumor portfolio reaching a key inflection point.** BGB-43395 (a selective CDK4 inhibitor) demonstrated promising preliminary efficacy in 1L HR+/HER2- breast cancer, supporting an imminent Phase 3 initiation. Combined with letrozole, BGB-43395 (400mg BID) delivered a 63.2% cORR, comparable to Pfizer's atirmociclib plus letrozole (67.6% ORR). Crucially, BGB-43395 exhibited a highly differentiated safety profile, reporting zero Grade ≥3 neutropenia (vs. 26.5% for atirmociclib) and manageable GI toxicities when administered with food in the 400mg BID cohort. We will continue to monitor these dynamics as patient follow-up matures. Furthermore, BeOne's GPC3/4-1BB bsAb, BGB-B2033, yielded impressive efficacy in 2L+ HCC. A potentially pivotal global expansion cohort in 2L+ HCC is currently ongoing, alongside exploratory studies in the 1L setting. These clinical milestones underscore the robust momentum of BeOne's solid tumor pipelines.
- **3SBio: Encouraging first mPFS readout for 707 in 1L PD-L1+ NSCLC.** ASCO 2026 revealed encouraging Phase 2 data for 707 (PF'4404), validating its competitiveness within the PD-(L)1/VEGF class. In 1L PD-L1+ NSCLC, 707 monotherapy delivered a 12.4-month median PFS, comparing favorably to ivonescimab on a cross-trial basis, with pronounced strength in the PD-L1 high (15.8 months) and non-squamous (12.4 months) subgroups. Additionally, 707 plus chemotherapy demonstrated highly promising preliminary efficacy in 1L pMMR endometrial cancer (EC), with cORRs exceeding 81%, outperforming the pembrolizumab plus chemotherapy standard of care (72.3%). With a manageable safety profile across both indications, we view these readouts as highly de-risking. Pfizer has registered eleven global studies for 707, including three global Ph3 studies across four 1L indications. We expect additional China Ph2 readouts of 707+chemo in 1L NSCLC and mCRC in 2H26 to serve as near-term catalysts for 3SBio.

Valuation Table

Name	Ticker	Rating	Mkt Cap (US$ mn)	TP (LC)	Upside/ Downside	P/E (x) FY27E	P/E (x) FY28E	P/B (x) FY27E	P/B (x) FY28E	ROE (%) FY27E	ROE (%) FY28E
3SBio	1530 HK	BUY	5,463.3	34.87	107%	22.9	20.4	1.1	1.1	0.1	0.1
Akeso	9926 HK	BUY	12,517.7	185.80	74%	116.7	52.1	9.6	8.4	0.1	0.2
BeOne Medicines	ONC US	BUY	32,554.5	392.43	43%	24.5	16.8	56.7	42.7	0.2	0.2
Innovent Biologics	1801 HK	BUY	17,458.0	113.86	44%	34.5	25.5	4.5	3.9	0.1	0.2
Kelun-Biotech	6990 HK	BUY	12,008.8	507.11	26%	nm	115.4	21.8	18.4	(0.1)	0.2

Source: Company data, CMBIGM estimates

Content

Akeso (9926 HK)

Ivonescimab in 1L sq-NSCLC

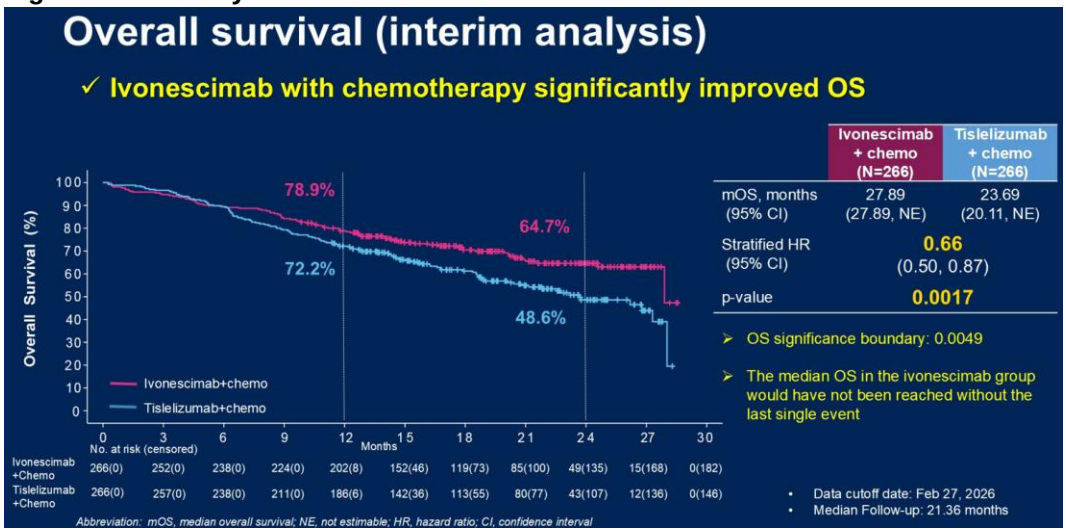
Data summary:

The interim overall survival analysis of Ivonescimab plus chemotherapy versus tislelizumab plus chemotherapy in advanced squamous non-small-cell lung cancer (HARMONi-6) were released (link).

HARMONi-6 is a double-blind, randomised, phase 3 trial, which was conducted at 50 hospitals across China. Patients aged 18–75 years with previously untreated, stage IIIB, IIIC, or stage IV squamous NSCLC were eligible for inclusion. Eligible patients were randomly assigned in a 1:1 ratio to receive ivonescimab or tislelizumab, in combination with paclitaxel and carboplatin for four cycles, followed by maintenance ivonescimab or tislelizumab monotherapy. The primary endpoint was progression-free survival assessed by the independent radiographic review committee. Overall survival was a key secondary endpoint.

From Aug 17, 2023, to Jan 21, 2025, a total of 532 patients were randomly allocated (266 per group). 494 (93%) of patients were male. The median age was 64 years (IQR 59–69). At data cutoff (Feb 27, 2026), with a median follow-up of 21.4 months, the median overall survival was 27.9 months (95% CI 27.89–not evaluable) with ivonescimab versus 23.7 months (20.11–NE) with tislelizumab (hazard ratio for death 0.66 [95% CI 0.50–0.87]; pone-sided=0.0017), meeting the prespecified boundary (p<0.0049). The overall survival benefit with ivonescimab plus chemotherapy was consistent across key subgroups. Treatment-related adverse events of grade 3 or higher occurred in 184 (69%) of 266 patients in the ivonescimab group and 156 (59%) of 265 patients in the tislelizumab group. The incidence of grade 3 or higher haemorrhage was seven (3%) of 266 and two (1%) of 265, respectively.

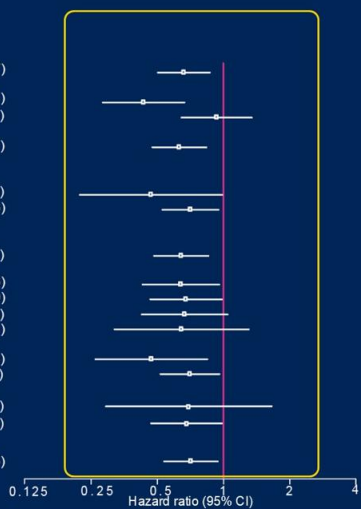
Figure 1: Summary of main clinical results of HARMONi-6 trial



Subgroup analysis of overall survival

✓ OS benefit was consistent across key subgroups

Charecteristic	Ivonescimab+chemo Events/Number of subjects	Tislelizumab+chemo Events/Number of subjects	Hazard ratio (95% CI)
Overall	84/266	120/266	0.66 (0.50, 0.87)
Age, years			
<65	31/135	63/139	0.43 (0.28, 0.67)
≥65	53/131	57/127	0.93 (0.64, 1.36)
Sex			
Male	79/256	110/238	0.63 (0.47, 0.84)
Female	5/10	10/28	
ECOG PS			
0	10/42	21/42	0.47 (0.22, 0.99)
1	74/224	99/222	0.71 (0.52, 0.96)
Disease Stage			
IIIB/IIIC	7/21	8/20	
IV	77/245	112/246	0.64 (0.48, 0.86)
PD-L1 TPS			
<1%	39/105	56/105	0.64 (0.43, 0.96)
≥1%	45/161	64/161	0.68 (0.46, 0.99)
1-49%	32/112	43/99	0.67 (0.42, 1.05)
≥50%	13/49	21/62	0.64 (0.32, 1.31)
≥3 metastases sites			
Yes	18/42	28/39	0.47 (0.26, 0.85)
No	66/224	92/227	0.70 (0.51, 0.97)
Liver metastases			
Yes	11/28	25/45	0.69 (0.34, 1.41)
No	73/238	95/221	0.68 (0.50, 0.92)
Brain metastases			
Yes	2/9	12/17	
No	82/257	108/249	0.71 (0.53, 0.95)



- Median OS and HR will not be reported for subgroups with fewer than 10 events

Safety summary

- Ivonescimab + chemo showed a manageable safety profile in squamous NSCLC

	Ivonescimab + chemo (N=266)	Tislelizumab + chemo (N=265)
TRAE	264 (99.2)	263 (99.2)
Grade ≥ 3 TRAE	**184 (69.2)**	**156 (58.9)**
Serious TRAE	110 (41.4)	91 (34.3)
Leading to ivonescimab or tislelizumab discontinuation	14 (5.3)	12 (4.5)
Leading to death	10 (3.8)	11 (4.2)
Grade ≥ 3 irAE#	**34 (14)**	**36 (14)**

- Data are n (%)
- # immune-related adverse events were assessed by investigators

Possibly VEGF-related adverse events

- Possibly VEGF-related AEs occurred more frequently in the ivonescimab arm, most of which were grade 1-2

Possibly VEGF-Related AEs#	Ivonescimab + chemo (N=266)				Tislelizumab + chemo (N=265)			
	Any Grade	Grade 1	Grade 2	Grade ≥3	Any Grade	Grade 1	Grade 2	Grade ≥3
Proteinuria	113 (42.5)	35 (13.2)	60 (22.6)	**18 (6.8)**	34 (12.8)	26 (9.8)	8 (3.0)	**0**
Haemorrhage	**66 (24.8)**	**39 (14.7)**	**20 (7.5)**	**7 (2.6)**	**32 (12.1)**	**24 (9.1)**	**6 (2.3)**	**2 (0.8)**
Hypertension	39 (14.7)	7 (2.6)	22 (8.3)	**10 (3.8)**	15 (5.7)	3 (1.1)	7 (2.6)	**5 (1.9)**
Arterial thromboembolism	4 (1.5)	1 (0.4)	0	**3 (1.1)**	0	0	0	**0**
Venous thromboembolism	2 (0.8)	0	2 (0.8)	**0**	3 (1.1)	0	2 (0.8)	**1 (0.4)**
Fistula	1 (0.4)	0	1 (0.4)	**0**	0	0	0	**0**

- # AE terms were grouped terms
- Data are n (%)

Source: ASCO, Summit, Akeso, CMBIGM

CMBI Comments:

Unprecedented dual efficacy: first global phase 3 to achieve both OS and PFS superiority over PD-1 + chemo. The HARMONi-6 trial marks a historic milestone, as it is the first Phase 3 study globally in the lung cancer space to demonstrate statistically significant dual positive results for both OS and PFS when comparing a PD-1/VEGF bsAb plus chemotherapy against the standard-of-care PD-1 plus chemotherapy. In the first-line treatment of sq-NSCLC, ivonescimab plus chemotherapy significantly reduced the risk of death by 34% compared to tislelizumab plus chemotherapy (HR=0.66, p=0.0017). These stellar OS results have exceeded the market expectations. Previously, in the pre-specified interim PFS analysis, the ivonescimab regimen achieved a clinically meaningful and statistically significant PFS benefit, delivering a median PFS of 11.1 months versus 6.9 months in the control arm (HR=0.60, p<0.0001). The newly released OS data effectively resolves the lingering market doubts regarding whether the robust PFS benefit could successfully translate into a definitive OS advantage.

Consistent efficacy across PD-L1 subgroups and robust control arm validation. The survival benefit of ivonescimab plus chemotherapy was highly consistent regardless of baseline PD-L1 expression levels. The treatment arm demonstrated significant OS benefits across all pre-specified subgroups: the PD-L1 TPS ≥1% subgroup yielded an OS HR of 0.68, while the TPS <1% subgroup delivered an HR of 0.64. Furthermore, the TPS 1-49% and TPS ≥50% subgroups posted HRs of 0.67 and 0.64, respectively. It is also crucial to highlight the high credibility of this clinical trial; the control arm (tislelizumab plus chemotherapy) achieved a median OS of 23.7 months, which aligns closely with the 22.8-month median OS observed in the benchmark Rationale-307 study (link). This consistent performance of the control arm underscores the genuine superiority of the ivonescimab regimen.

Caveats remain on data maturity and efficacy in elderly patients. While the headline data is exceptionally strong, there are a few nuances to monitor as the data matures or in other global trials. Notably, the median follow-up time of 21.4 months is currently shorter than the median OS of both the ivonescimab arm (27.9 months) and the control arm (23.7 months), indicating that the data maturity requires further follow-up for the final analysis. Additionally, in the subgroup of patients aged 65 years and older, ivonescimab did not demonstrate a statistically significant survival benefit, yielding an HR of 0.93 (95% CI: 0.64, 1.36), potentially due to the baseline imbalance in the elderly cohorts between the two arms according to the Summit management. Given that Chinese sq-NSCLC patients are generally younger than their Western counterparts, the results of the global Phase 3 HARMONi-3 trial will be crucial to confirm the OS benefit in elderly populations. Despite these caveats, the overall clinical profile remains highly compelling. We believe that ivonescimab is well-positioned to establish itself as the new foundational immuno-oncology (IO) cornerstone, gradually replacing traditional PD-1 plus chemotherapy regimens starting in China and eventually expanding globally as further validation is achieved.

Manageable safety profile with controlled hemorrhage risks. The overall safety profile of ivonescimab plus chemotherapy remains manageable and is broadly comparable to that of tislelizumab plus chemotherapy. The incidence of Grade ≥3 TRAEs was higher in the experimental arm (69.2% vs 58.9%), which is an expected outcome given the addition of VEGF inhibition. Importantly, the rates of adverse events leading to treatment discontinuation or death were similar between the two groups (5.3% vs 4.5%). A key safety metric of interest for VEGF-targeting agents in squamous histology is the risk of bleeding; in this trial, the incidence of Grade ≥3 hemorrhage was 2.6% in the ivonescimab group compared to 0.8% in the control group. Although slightly elevated, this remains at a low absolute level, confirming that the safety risks are well-controlled and acceptable given the profound survival benefits.

Global Phase 3 HARMONi-3 readout in 2H26. Looking ahead, the overseas development of ivonescimab continues to progress steadily. Previously, according to Akeso's partner Summit Therapeutics the first interim PFS analysis for the overseas HARMONi-3 trial (in the sq-NSCLC cohort) did not reach statistical significance. However, the trial remains blinded and is continuing as planned. We expect the final PFS results and the interim OS analysis to be released in the second half of 2026, which will serve as a critical catalyst to answer market questions regarding whether the exceptional data generated in China can be replicated in Western populations. Additionally, ivonescimab is approaching a major regulatory milestone in the US, with the FDA expected to issue its final review decision by November 14, 2026, based on the HARMONi study in EGFR-mutated NSCLC.

Kelun-Biotech (6990 HK)

Sac-TMT in 1L PD-L1+ NSCLC

Data Summary:

The results from the planned interim analysis for PFS in this phase 3 OptiTROP-Lung05 study (NCT06448312) were reported (link). The trial evaluates sacituzumab tirumotecan (sac-TMT) plus pembrolizumab (P) versus pembrolizumab (P) as first-line treatment for PD-L1-positive advanced NSCLC.

Eligible patients (pts) had treatment-naïve, locally advanced or metastatic NSCLC without EGFR/ALK alterations and positive PD-L1 expression (defined as TPS ≥1%). Pts were stratified by PD-L1 (TPS 1-49% vs ≥ 50%), histology (squamous vs non-squamous) and ECOG (0 vs 1) and then randomized (1:1) to receive sac-TMT 4 mg/kg Q2W plus P 400 mg Q6W or P 400 mg Q6W. The primary endpoint was PFS per RECIST 1.1 assessed by blinded independent central review (BICR), and the key secondary endpoint was OS.

A total of 413 pts (median age 65 yrs; 84.5% ECOG 1; 40.0% squamous; 40.0% PD-L1 TPS ≥ 50%) were randomized to receive sac-TMT + P (n = 208) or P (n = 205). As of Sep 29, 2025, the median follow-up was 10.5 months. PFS by BICR was significantly longer in the sac-TMT + P group than the P group (median, not reached vs 5.7 months; HR, 0.35; 95% CI, 0.26-0.47; p< 0.0001). The data for OS were not mature, and a favorable trend was observed in the sac-TMT + P group (HR, 0.55; 95% CI, 0.36-0.85). The BICR-assessed ORR was 70.2% in the sac-TMT + P group versus 42.0% in the P group.

In the pre-specified PD-L1 subgroups, the HRs for PFS in pts with TPS 1-49% and TPS ≥ 50% were 0.28 (95% CI, 0.19-0.41) and 0.47 (95% CI, 0.29-0.77).

In the pre-specified histology subgroups, the HRs for PFS in pts with non-squamous and squamous were 0.28 (95% CI, 0.18-0.43) and 0.44 (95% CI, 0.29-0.66).

Grade ≥ 3 TEAEs were 55.3% in the sac-TMT + P group and 31.4% in the P group. Most common grade ≥3 TEAEs of special interest for sac-TMT were neutrophil count decreased (17.3%), anemia (9.1%), and stomatitis (5.3%). TEAEs led to discontinuation of sac-TMT/ pembrolizumab in 3.8%/5.3% of pts in the sac-TMT + P group while discontinuation of pembrolizumab occurred in 4.9% of pts in the P group.

Figure 2: Summary of main clinical results of OptiTROP-Lung05 trial

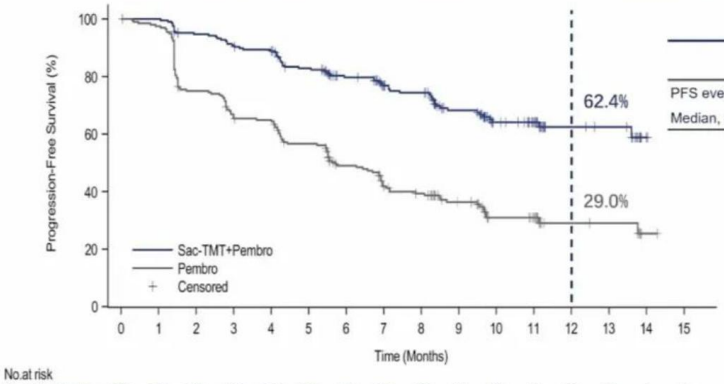
Baseline Characteristics

Characteristic		Sac-TMT + Pembro (n = 208)	Pembro (n = 205)
Age	Median (range), years	64 (28, 75)	65 (22, 75)
	≥ 65	101 (48.6)	108 (52.7)
Sex	Male	166 (79.8)	174 (84.9)
ECOG score	1	176 (84.6)	173 (84.4)
Smoking history	Current or former	166 (79.8)	176 (85.9)
	Never	42 (20.2)	29 (14.1)
Histology	Adenocarcinoma	122 (58.7)	123 (60.0)
	Squamous cell carcinoma	85 (40.9)	80 (39.0)
	Other[a]	1 (0.5)	2 (1.0)
Clinical stage	IIIB/IIIC	14 (6.7)	13 (6.3)
	IV	194 (93.3)	192 (93.7)
PD-L1 TPS	1-49%	125 (60.1)	123 (60.0)
	≥50%	83 (39.9)	82 (40.0)
Metastases	Brain	7 (3.4)	6 (2.9)
	Liver	21 (10.1)	23 (11.2)
	≥ 3 Distant metastatic sites	60 (28.8)	55 (26.8)

[a] Included one NSCLC (not otherwise specified) in the sac-TMT + pembro group, and one mucoepidermoid carcinoma and one thymoma in the pembro group.

PFS by BICR

Sac-TMT + pembro significantly improved PFS vs. pembro, with a 65% reduction in risk of disease progression or death



No.at risk

Sac-TMT+Pembro	208	208	195	187	182	164	144	126	120	90	62	47	20	18	1	0
Pembro	205	195	149	129	127	108	84	67	61	46	28	24	9	8	1	0

	Sac-TMT + Pembro (n = 208)	Pembro (n = 205)
PFS events, n (%)	66 (31.7)	128 (62.4)
Median, mo (95%CI)	NR (13.6, NE)	5.7 (4.3, 7.0)

HR 0.35 (95%CI: 0.26, 0.47)

***p* < 0.0001[a]**

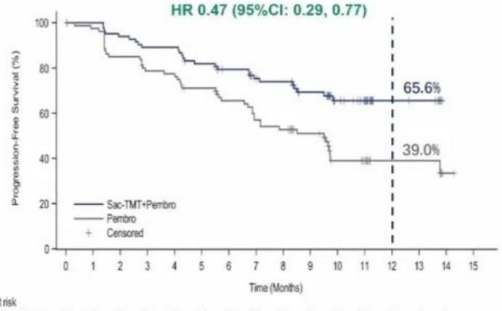
[a] Updated efficacy boundary (corresponding to actual PFS events of 194): 0.0174 (2-sided).
NE, not estimable; NR, not reached.

PFS (BICR) by PD-L1 Expression

TPS ≥ 50%

	Sac-TMT + Pembro (n = 83)	Pembro (n = 82)
PFS events, n (%)	26 (31.3)	44 (53.7)
Median, mo (95%CI)	NR (NE, NE)	9.5 (6.9, 13.8)

HR 0.47 (95%CI: 0.29, 0.77)



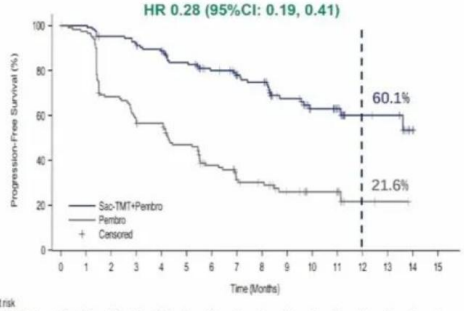
No.at risk

Sac-TMT+Pembro	83	83	76	74	74	67	60	53	51	42	28	22	9	8	0
Pembro	82	78	68	62	61	55	46	40	37	30	17	14	7	7	1	0

TPS 1-49%

	Sac-TMT + Pembro (n = 125)	Pembro (n = 123)
PFS events, n (%)	40 (32.0)	84 (68.3)
Median, mo (95%CI)	NR (11.1, NE)	4.3 (2.9, 5.5)

HR 0.28 (95%CI: 0.19, 0.41)



No.at risk

Sac-TMT+Pembro	125	125	117	113	108	97	84	73	69	48	34	25	11	10	1	0
Pembro	123	117	81	67	66	53	38	27	24	16	11	10	2	1	0	

Summary of Safety

Event, n (%)	Sac-TMT + Pembro (n = 208)		Pembro (n = 204)	
	Any grade	Grade ≥3	Any grade	Grade ≥3
Treatment-emergent AEs	207 (99.5)	115 (55.3)	178 (87.3)	64 (31.4)
Serious	81 (38.9)	—	59 (28.9)	—
Led to discontinuation of sac-TMT/ pembro	8 (3.8) / 11 (5.3)	—	10 (4.9)	—
Led to death	5 (2.4)	—	13 (6.4)	—
Common TEAEs[a]				
Anemia	182 (87.5)	19 (9.1)	55 (27.0)	2 (1.0)
Alopecia	137 (65.9)	0	6 (2.9)	0
White blood cell count decreased	96 (46.2)	18 (8.7)	5 (2.5)	1 (0.5)
Neutrophil count decreased	93 (44.7)	36 (17.3)	3 (1.5)	1 (0.5)
Stomatitis	84 (40.4)	11 (5.3)	3 (1.5)	0
Decreased appetite	73 (35.1)	2 (1.0)	27 (13.2)	0
Weakness	71 (34.1)	8 (3.8)	23 (11.3)	2 (1.0)
Nausea	70 (33.7)	0	11 (5.4)	0
Hypoalbuminemia	61 (29.3)	0	35 (17.2)	0
Weight decreased	56 (26.9)	1 (0.5)	19 (9.3)	1 (0.5)
ALT increased	55 (26.4)	1 (0.5)	33 (16.2)	0
Rash	50 (24.0)	6 (2.9)	33 (16.2)	1 (0.5)

- Median duration of exposure
  - Sac-TMT + Pembro: Sac-TMT 8.9 months/ Pembro 8.3 months
  - Pembro alone: 5.1 months
- Higher incidence of grade ≥3 TEAEs with sac-TMT+ pembro vs. pembro, primarily driven by expected hematologic AEs of sac-TMT
- Treatment-emergent AEs leading to discontinuation of pembro were similar in both groups. No treatment-related deaths were attributed to sac-TMT

[a] Summary of any grade TEAEs with incidence ≥ 20% in either treatment group.
ALT increased, alanine aminotransferase increased; TEAE, treatment-emergent adverse events.

Adverse Events of Special Interest

AEOSIs were consistent with the known profiles of the individual agents, and no new safety signals were identified

Sac-TMT AEOSI

	Sac-TMT + Pembro (n = 208)	
	Any grade	Grade ≥3
Anemia	181 (87.0)	19 (9.1)
Neutrophil count decreased[b]	94 (45.2)	40 (19.2)
Stomatitis[c]	92 (44.2)	13 (6.3)
Ocular surface toxicity[d]	30 (14.4)	0
Infusion-related reaction[e]	12 (5.8)	0

Pembro AEOSI[a]

	Sac-TMT + Pembro (n = 208)		Pembro (n = 204)	
	Any grade	Grade ≥3	Any grade	Grade ≥3
Hypothyroidism	28 (13.5)	0	23 (11.3)	0
Pneumonitis[f]	26 (12.5)	6 (2.9)	15 (7.4)	2 (1.0)
Hyperthyroidism	15 (7.2)	0	10 (4.9)	0
Infusion reaction[e]	12 (5.8)	0	2 (1.0)	0
Severe skin reactions	6 (2.9)	6 (2.9)	3 (1.5)	3 (1.5)
Adrenal insufficiency	5 (2.4)	3 (1.4)	2 (1.0)	0

[a] Summary of any grade AEOSI for pembro with incidence ≥ 2% in either treatment group. [b] Including 5 patients (2.4%) with febrile neutropenia. [c] Stomatitis includes the preferred terms of stomatitis, oral ulcer and aphthous ulcer. [d] The most common ocular surface toxicities included dry eye (10.1%), conjunctivitis (5.8%), and increased tearing (3.4%). [e] Infusion reactions occurred during the course of sac-TMT infusion. [f] Pneumonitis includes the preferred terms of pneumonitis, immune-mediated lung disease, and interstitial lung disease. The exposure-adjusted incidence rates (patients with AEOSI / patient-years) of all-grade pneumonitis were 0.173 in the sac-TMT + pembro group and 0.144 in the pembro group.
AEOSI, adverse events of special interest.

Source: ASCO, Kelun-Biotech, CMBIGM

CMBI Comments:

Stellar efficacy profile with favorable cross-trial comparisons. The OptiTROP-Lung05 study marks a historic milestone, as the first Phase 3 trial to validate the "ADC + IO" regimen as a potent first-line therapy for NSCLC. In this 1L PD-L1≥1% NSCLC setting, the control arm performed comparably to that of Akeso's ivonescimab HARMONi-2 trial (link), validating the baseline patient population (ORR: 42.0% vs 38.5%; mPFS: 5.7 months vs 5.82 months, respectively). Against this baseline, sac-TMT + pembrolizumab delivered an impressive PFS HR of 0.35, which compares favorably to the 0.51 PFS HR observed with ivonescimab versus pembrolizumab. While the mPFS for the combination arm is not yet reached, Kelun-Biotech estimates it could reach approximately 16.7 months. This anticipated 16.7-month mPFS notably outshines the 11.14 months seen in the HARMONi-2 trial. Furthermore, in cross-trial comparisons, this efficacy surpasses the standard PD-1 + chemotherapy regimen; for instance, in the Rationale-304 trial, tislelizumab plus chemotherapy delivered a mPFS of 14.6 months for TPS≥50% non-squamous NSCLC and 9.7 months for TPS 1-49%. This underscores a synergistic effect when combining a TROP2 ADC with a PD-1 inhibitor compared to traditional chemo-immunotherapy.

Robust benefit across PD-L1 and histology subgroups. The combination therapy demonstrated consistency across pre-specified subgroups, further highlighting its superiority in cross-trial comparisons. For patients with PD-L1 TPS 1-49% and TPS ≥50%, the sac-TMT + pembrolizumab regimen delivered PFS HRs of 0.28 and 0.47, respectively. These figures are stronger than the 0.54 and 0.48 HRs reported in the ivonescimab HARMONi-2 trial for the same subgroups, in cross-trial comparisons. Similarly, in histology-based subgroups, the sac-TMT plus pembrolizumab combination yielded PFS HRs of 0.28 for non-squamous and 0.44 for squamous NSCLC, both of which track better than the corresponding subgroup data for ivonescimab monotherapy. Nevertheless, besides direct competition with the PD-1/VEGF bsAb, we also see synergy of sac-TMT in combination with PD-1/VEGF bsAb for first-line treatment of broad indications.

Manageable safety profile. While the efficacy is strong, it is important to keep in mind that the sac-TMT + pembrolizumab regimen involves two distinct therapeutic agents, whereas ivonescimab is a single bispecific antibody. The safety profile of the combination was generally manageable and consistent with the known profiles of both components. However, Grade ≥3 TEAEs were higher in the combo arm (55.3% vs 31.4%). Notably, Grade ≥3 stomatitis occurred in 6.3% of patients in the combo arm. Consequently, the discontinuation rate for the two-drug regimen was slightly higher, as expected, totaling 9.1% (3.8% for sac-TMT and 5.3% for pembrolizumab), compared to just a 1.5% discontinuation rate due to TRAEs for the single-agent ivonescimab in the HARMONi-2 trial.

Eyes on development of sac-TMT in next-generation combinations. MSD/Kelun-Biotech have not yet initiated a Phase 3 trial comparing sac-TMT against the broader SoC (PD-1 + chemotherapy), a space where PD-1/VEGF bispecifics are currently mounting a direct challenge. Looking ahead, the competitive landscape for TROP2 ADCs in 1L NSCLC will be further clarified by AstraZeneca's AVANZAR trial (Dato-DXd + PD-L1 mAb + chemo vs pembrolizumab + chemo in 1L NSCLC) results expected in 2H26, which will provide critical insights into the development of TROP2 ADC in 1L all-comer population. Additionally, capitalizing on the strong synergy observed between PD-1 and sac-TMT—and noting the overall survival benefits of PD-1/VEGF bispecifics plus chemotherapy in 1L squamous NSCLC—Kelun-Biotech is strategically planning to initiate trials of sac-TMT combined with its in-licensed PD-1/VEGF bsAb CR-001, especially for 1L non-squamous NSCLC. Similarly, we anticipate MSD to explore the combination of sac-TMT with its own PD-1/VEGF asset MK-2010.

Innovent (1801 HK)

IBI363 in 1L NSCLC

Data Summary:

Phase 1 study evaluating IBI363 plus platinum-based doublet-chemotherapy (PDC, pemetrexed/paclitaxel plus platinum) in 1L NSCLC was presented. Previously untreated pts with advanced NSCLC, without sensitizing EGFR, ALK, or ROS1 alterations were enrolled. The safety lead-in evaluated IBI363 at 1.5 or 3 mg/kg Q3W plus PDC. In dose optimization (PD-L1 TPS < 50% required), pts were randomized 1:1:1 to 3 cohorts: 3-1.5 mg/kg (IBI363 3 mg/kg plus PDC in cycle 1, then 1.5 mg/kg Q3W plus PDC in subsequent cycles), 3 mg/kg (IBI363 3 mg/kg Q3W plus PDC) and 1.5 mg/kg (IBI363 1.5 mg/kg Q3W plus PDC). Stratification factors were squamous vs non-squamous, and PD-L1 TPS < 1% vs 1-49%.

As of December 22, 2025, 80 pts were enrolled in safety lead-in (N = 11) and dose optimization (N = 69) with median follow-up (mFU) of 5.8 months (range: 0.9-9.5). Baseline characteristics (median age: 64 years, male: 88.8%, ECOG PS 1: 81.3%, stage IV: 72.5%, sqNSCLC: 66.3%) were balanced among 3-1.5 mg/kg (N = 23), 1.5 mg/kg (N = 28) and 3 mg/kg (N = 29) cohorts. Median treatment duration of IBI363 was 25.0 weeks (range: 4.0-41.1) while 65.0% pts with ongoing treatment, and 88.9% pts having completed ⩾4 cycles of PDC.

Grade⩾3 (G3+) TEAEs occurred in 81.3% pts including 65.2% for 3-1.5 mg/kg, 82.1% for 1.5 mg/kg and 93.1% for 3 mg/kg cohorts. Common TEAEs were anemia (any grades 78.8%, G3+ 18.8%), neutrophil count decrease (75.0%, G3+ 42.5%), white blood cell count decrease (63.8%, G3+ 20.0%), arthralgia (51.3%, G3+ 2.5%), and platelet count decrease (45.0%, G3+ 17.5%). IBI363-related AEs led to corresponding treatment discontinuation and death in 6.3% and 1.3% pts. In dose optimization, 65.2% pts had PD-L1 TPS < 1 and 34.8% had TPS 1-49%.

Efficacy was evaluable in 62 pts with at least 1 tumor assessment. For 3-1.5 mg/kg cohort (N = 22), ORR was 86.4% (95% CI: 65.1-97.1, cORR: 81.8%) and DCR was 100% (95% CI: 84.6-100). ORR was 85.7% for sqNSCLC (N = 14) and 87.5% for non-sqNSCLC (N = 8). For the 1.5 mg/kg (N = 19) and 3 mg/kg cohorts (N = 21), ORR was 57.9% (cORR: 42.1%) and 66.7% (cORR: 57.1%). PFS was immature (events 28.8%). Clinical PK data also supported an optimal benefit-risk profile based on efficacy and safety observed at 3-1.5 mg/kg.

Figure 3: Summary of main clinical results of IBI363 plus chemo in 1L NSCLC

- As of the data cutoff date, Dec 22, 2025, a total of 80 patients had been enrolled (all *EGFR* wild-type)
- 11 patients enrolled in the safety lead-in phase and 69 patients in the dose optimization phase.
- **The median follow-up time was 5.8 months (range: 0.9–9.5 months).**
- The median age was 64 years, 88.8% were male, 81.3% had an ECOG PS score of 1, and 66.3% were squamous NSCLC.
- The baseline characteristics of patients in the three dose groups were balanced and comparable.
- **In the dose optimization part, NSCLC patients with PD-L1 TPS < 50% were enrolled, of which 65.2% had PD-L1 TPS < 1% and 34.8% had TPS 1–49%.**

	3→1.5 mg/kg (n=23)	1.5 mg/kg (n=28)	3 mg/kg (n=29)	Total (N=80)
Median age at screening, years (range)	64.0 (54–72)	62.5 (49–75)	67.0 (55–75)	64.0 (49–75)
Gender, n (%)				
Male	19 (82.6)	25 (89.3)	27 (93.1)	71 (88.8)
Female	4 (17.4)	3 (10.7)	2 (6.9)	9 (11.3)
ECOG PS, n (%)				
0	1 (4.3)	4 (14.3)	10 (34.5)	15 (18.8)
1	22 (95.7)	24 (85.7)	19 (65.5)	65 (81.3)
Smoking status, n (%)				
Current	3 (13.0)	4 (14.3)	2 (6.9)	9 (11.3)
Former	15 (65.2)	20 (71.4)	23 (79.3)	58 (72.5)
Never	5 (21.7)	4 (14.3)	4 (13.8)	13 (16.3)
Histological classification, n (%)				
Adenocarcinoma	8 (34.8)	9 (32.1)	10 (34.5)	27 (33.8)
Squamous cell carcinoma	15 (65.2)	19 (67.9)	19 (65.5)	53 (66.3)
PD-L1 TPS, n (%)				
<1%	14 (60.9)	15 (53.6)	20 (69.0)	49 (61.3)
1–49%	8 (34.8)	12 (42.9)	8 (27.6)	28 (35.0)
≥50%	0	1 (3.6)	0	1 (1.3)
Missing	1 (4.3)	0	1 (3.4)	2 (2.5)

Overview of TEAEs	Total (N=80)	1.5 mg/kg (n=28)	3 mg/kg (n=29)	3→1.5 mg/kg (n=23)
TEAEs, n (%)	80 (100)	28 (100)	29 (100)	23 (100)
Grade ≥3 TEAEs	65 (81.3)	23 (82.1)	27 (93.1)	15 (65.2)
TRAEs, n (%)	79 (98.8)	27 (96.4)	29 (100)	23 (100)
Grade ≥3 TRAEs	60 (75.0)	21 (75.0)	25 (86.2)	14 (60.9)
IBI363/TAK-928-related TEAEs	79 (98.8)	27 (96.4)	29 (100)	23 (100)
Grade ≥3 IBI363/TAK-928-related TEAEs	44 (55.0)	14 (50.0)	20 (69.0)	10 (43.5)
IBI363/TAK-928-related AEs leading to treatment discontinuation	5 (6.3)	1 (3.6)	2 (6.9)	2 (8.7)
IBI363/TAK-928-related AEs leading to death*	1 (1.3)	1 (3.6)*	0	0

*One patient in the 1.5 mg/kg cohort died due to dyspnea.
AE, adverse event; TEAE, treatment-emergent adverse event; TRAE, treatment-related adverse event.

	3→1.5 mg/kg (n=23)		Total (N=80)	
	All grade	Grade ≥3	All grade	Grade ≥3
Patients with any TEAE, n (%)	23 (100)	15 (65.2)	80 (100)	65 (81.3)
Anemia	19 (82.6)	5 (21.7)	63 (78.8)	15 (18.8)
Neutrophil count decreased	15 (65.2)	7 (30.4)	60 (75.0)	34 (42.5)
White blood cell count decreased	14 (60.9)	4 (17.4)	51 (63.8)	16 (20.0)
Arthralgia	13 (56.5)	0	41 (51.3)	2 (2.5)
Platelet count decreased	5 (21.7)	4 (17.4)	36 (45.0)	14 (17.5)
AST increased	12 (52.2)	0	32 (40.0)	0
Hypoalbuminemia	9 (39.1)	0	32 (40.0)	0
Rash	3 (13.0)	0	31 (38.8)	4 (5.0)
Hypothyroidism	6 (26.1)	0	30 (37.5)	1 (1.3)
Hyponatremia	9 (39.1)	0	28 (35.0)	2 (2.5)
ALT increased	6 (26.1)	0	28 (35.0)	0
Hyperthyroidism	8 (34.8)	0	26 (32.5)	0
Nausea	7 (30.4)	0	26 (32.5)	2 (2.5)
Decreased appetite	7 (30.4)	0	25 (31.3)	0
Protein urine present	3 (13.0)	0	25 (31.3)	0
Hypocalcemia	3 (13.0)	0	20 (25.0)	0
Asthenia	6 (26.1)	0	19 (23.8)	1 (1.3)
Blood LDH increased	6 (26.1)	0	19 (23.8)	0
Weight decreased	5 (21.7)	0	19 (23.8)	1 (1.3)
Vomiting	6 (26.1)	0	18 (22.5)	1 (1.3)
Hypokalemia	3 (13.0)	0	17 (21.3)	2 (2.5)
Hyperglycemia	3 (13.0)	0	17 (21.3)	0
Hypochloremia	3 (13.0)	0	16 (20.0)	1 (1.3)

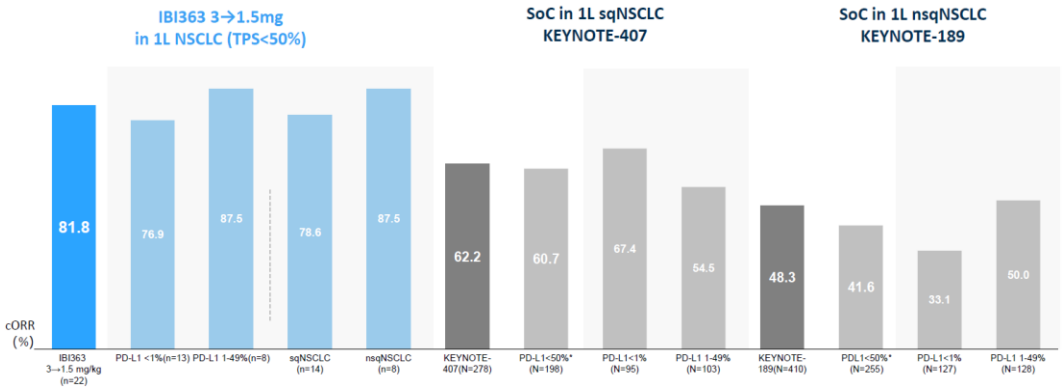
ALT, alanine aminotransferase; AST, aspartate aminotransferase; LDH, lactate dehydrogenase.

Efficacy in dose optimization*	1.5 mg/kg (n=19)	3 mg/kg (n=21)	3→1.5 mg/kg (n=22)
Confirmed best overall response, n (%)			
PR	8 (42.1)	12 (57.1)	18 (81.8)
SD	10 (52.6)	9 (42.9)	4 (18.2)
PD	1 (5.3)	0	0
Confirmed ORR (95% CI)	42.1% (20.3–66.5)	57.1% (34.0–78.2)	81.8% (59.7–94.8)
Unconfirmed ORR (95% CI)	57.9% (33.5–79.7)	66.7% (43.0–85.4)	86.4% (65.1–97.1)
DCR (95% CI)	94.7% (74.0–99.9)	100% (83.9–100.0)	100% (84.6–100.0)

* 7 patients were not evaluable at data cutoff

Efficacy at 3→1.5 mg/kg by subtype and PD-L1 TPS*	sqNSCLC (n=14)	non-sqNSCLC (n=8)	PD-L1 TPS <1% (n=13)	PD-L1 TPS 1–49% (n=8)
Confirmed best overall response, n (%)				
PR	11 (78.6)	7 (87.5)	10 (76.9)	7 (87.5)
SD	3 (21.4)	1 (12.5)	3 (23.1)	1 (12.5)
PD	0	0	0	0
Confirmed ORR (95% CI)	78.6% (49.2–95.3)	87.5% (47.3–99.7)	76.9% (46.2–95.0)	87.5% (47.3–99.7)
Unconfirmed ORR (95% CI)	85.7% (57.2–98.2)	87.5% (47.3–99.7)	76.9% (46.2–95.0)	100% (63.1–100.0)
DCR (95% CI)	100% (76.8–100.0)	100% (63.1–100.0)	100% (75.3–100.0)	100% (63.1–100.0)

*At 3→1.5 mg, PD-L1 TPS was missing in 1 patient and 1 patient was not evaluable at data cutoff.



Source: ASCO, Innovent, CMBIGM

CMBI Comments:

A major step in dose selection in 1L NSCLC. The Phase 1 data release marks a major step in the dose selection for IBI363 (TAK-928) in 1L NSCLC. The 3-1.5 mg/kg step-down cohort demonstrated optimal comprehensive benefits and was selected as the recommended regimen for further 1L studies. Efficacy in this cohort (N=22) was strong, delivering a confirmed ORR of 81.8%, with consistent responses across both squamous (85.7% ORR) and non-squamous (87.5% ORR) histologies. We view this as competitive compared to the historical standard of care; for context, Keytruda plus chemotherapy delivered ORRs of 48.3% and 62.2% in the KEYNOTE-189 and KEYNOTE-407 Phase 3 trials for 1L nsq- and sq-NSCLC, respectively.

Manageable safety profile with toxicities mainly chemotherapy-related. The safety profile of the 3-1.5 mg/kg cohort proved manageable. The 65.2% rate of Grade ⩾3 TEAEs compares favorably to the 72.8% and 74.8% rates observed in the KEYNOTE-189 and KEYNOTE-407 trials. The majority of these Grade ⩾3 TEAEs were hematologic toxicities (such as neutropenia and anemia) mostly related to the chemotherapy. Crucially, IBI363-related AEs led to treatment discontinuation in 8.7% of patients in the 3-1.5 mg/kg cohort, with no IBI363-related deaths reported. While any-grade arthralgia occurred in 56.5% of patients, there were no Grade 3 or higher cases, highlighting a well-tolerated clinical profile.

Advancing to a head-to-head trial. Based on these robust results, Innovent is advancing a head-to-head Phase 1 trial evaluating IBI363 (3-1.5 mg/kg) plus chemotherapy versus pembrolizumab plus chemotherapy in 1L NSCLC, regardless of PD-L1 expression levels (n=190). Looking ahead, we anticipate the potential initiation of a global 1L NSCLC Phase 3 study by Innovent/Takeda, following the positive PoC data readout.

Updated results for IBI363 in IO-resistant NSCLC remain robust. In a heavily pretreated patient population (72.1% having received ⩾2 prior lines of therapy), IBI363 monotherapy at 3mg/kg Q3W delivered a promising mPFS of 10.1 months and an mOS of 18.2 months

in the sq-NSCLC cohort (n=31). Efficacy in the nsq-NSCLC (n=25) cohort was also encouraging, achieving an mPFS of 4.2 months and an mOS of 15.2 months, both of which compare favorably against the current standard-of-care docetaxel (historical mPFS of 3.6 months and mOS of 12.3 months). Notably, a smaller proportion of patients in the nsq-NSCLC cohort were smokers (58%) compared to typical global trials (80–90%). This demographic nuance is clinically significant, as IBI363 demonstrated a substantially enhanced survival benefit in smokers, who achieved an impressive mOS of 23.4 months across all dose levels compared to 11.5 months for non-smokers. Bolstered by these strong efficacy signals, Innovent is currently conducting a global multi-regional Phase 3 trial in IO-resistant sq-NSCLC, with a separate Phase 3 study in nsq-NSCLC also in the planning stages.

BeOne Medicines (ONC US)

CDK4 inhibitor in 1L BC

Data Summary:

The Phase 1 data of frontline treatment (1L tx) with the selective CDK4 inhibitor BGB-43395 in combination with letrozole for metastatic HR+/HER2- breast cancer (BC) were released. In safety expansion cohort 2, CDK4/6i-naive pts with advanced/metastatic HR+/HER2− BC were randomized to receive BGB-43395 240, 400, or 600 mg PO BID + letrozole to determine the recommended dose for further development.

As of Nov 11, 2025, 58 pts received study tx (240 mg n = 19; 400 mg n = 19; 600 mg n = 20). TEAEs occurred in 98% of pts; grade (G)≥3 TEAEs in 32%, 37%, and 65% of pts on 240 mg, 400 mg, and 600 mg, respectively. The most common TEAEs (mostly G1/2) were (240 mg / 400 mg / 600 mg): diarrhea (79% / 95% / 90% [G3 5% / 11% / 30%]), nausea (53% / 68% / 85% [G3 0% / 5% / 0%]), and vomiting (26% / 47% / 60% [G3 0% / 0% / 0%]). Rates of TEAE hematologic toxicities (mostly G1/2) were low; neutrophil count decreased/neutropenia (240 mg 26% [G3 0%]; 400 mg 21% [G3 0%]; 600 mg 20% [G3 10%]); anemia (240 mg 5% [G3 0%]; 400 mg 21% [G3 0%]; 600 mg 20% [G3 5%]); platelet count decreased/thrombocytopenia ([all G1 or 2] 240 mg 5%; 400 mg 0%; 600 mg 5%).

Figure 4: Summary of clinical response of BGB-43395 plus letrozole in 1L BC

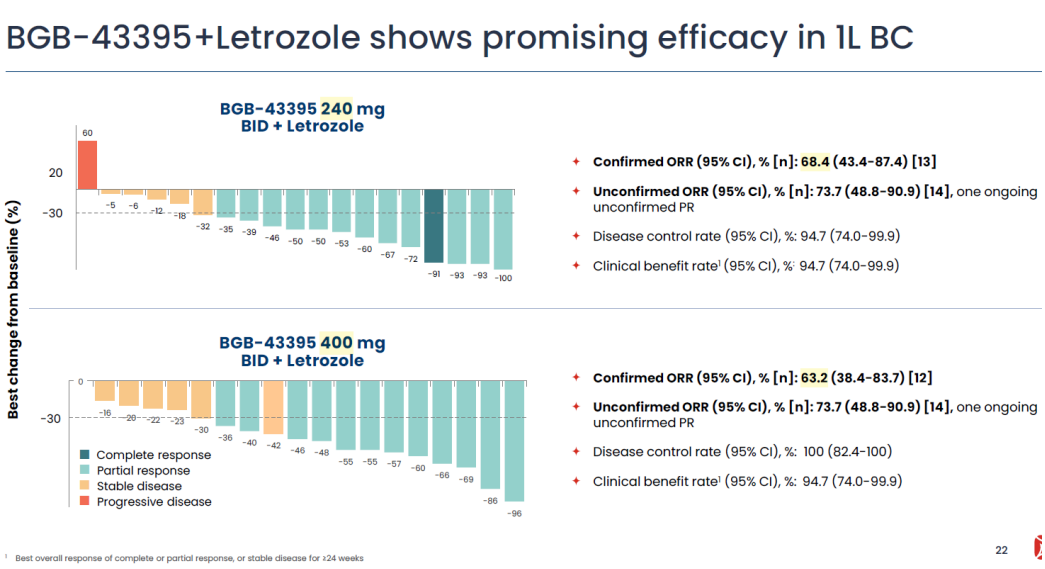
BGB-43395 BID dose + letrozole	240 mg (n=19)	400 mg (n=19)	600 mg (n=20)
Median tx follow-up, mo	7.0	7.1	5.2
Best overall response, %			
PR[a]	58	68	40
SD	37	32	55
PD	5	0	0
NE	0	0	5
Objective response rate (CR + PR), % (95% CI)	58(33-80)	68(43-87)	40(19-64)
Disease control rate (CR + PR + SD), % (95% CI)	95(74-100)	100(82-100)	95(75-100)

RECIST v1.1 (investigator). [a]Unconfirmed.

Source: ASCO, BeOne Medicines, CMBIGM. Note: ASCO abstract data, as of Nov 11, 2025.

As of Apr 30, 2026, BeOne reported the updated data of this trial as bellow (link1, link2):

Figure 5: Updated clinical data of BGB-43395 plus letrozole in 1L BC

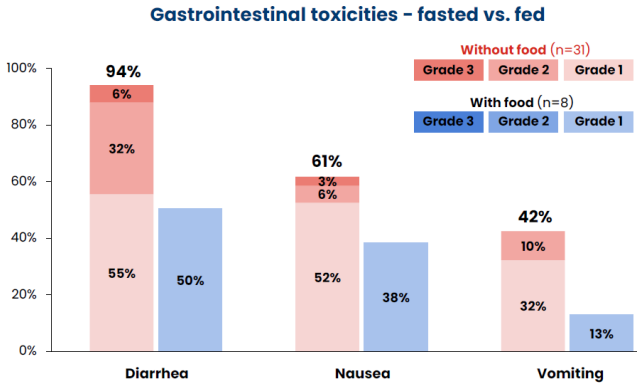


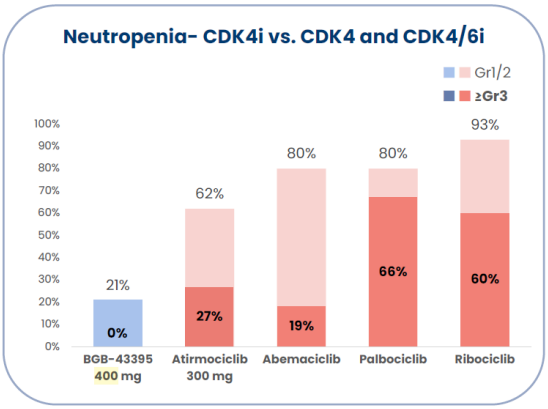
Hematologic TRAEs by dose arm

Hematologic adverse event, n (%)	240 mg BID + letrozole (n=19)		400 mg BID + letrozole (n=19)		600 mg BID + letrozole (n=20)	
	All grades	Grade ≥3	All grades	Grade ≥3	All grades	Grade ≥3
Neutrophil count decreased and/or Neutropenia	5 (26.3)	1 (5.3)	4 (21.1)	0	4 (20.0)	2 (10.0)
Platelet count decreased and/or Thrombocytopenia	1 (5.3)	0	0	0	1 (5.0)	0
Anemia	2 (10.5)	0	6 (31.6)	0	4 (20.0)	1 (5.0)

Substantial mitigation of GItoxicities with concurrent administration with food

- During the first 2 cycles, 1L mBC patients treated with BGB-43395 **400 mg** BID + letrozole experienced fewer and milder GI AEs when administered with food
- Additional mitigations under investigation include low-dose prophylactic anti-diarrheals and step-up dosing





Source: BeOne Medicines, CMBIGM. Note: BeOne presentation data, as of Apr 30, 2026.

CMBI Comments：

Competitive frontline efficacy supports Phase 3 advancement. BGB-43395 demonstrated promising preliminary anti-tumor activity in the first-line treatment of HR+/HER2- breast cancer. In the safety expansion cohort evaluating BGB-43395 in combination with letrozole, the 400mg BID dose – which has been selected for the upcoming Phase 3 study – delivered a cORR of 63.2%. This efficacy is highly comparable to that of Pfizer's CDK4-selective inhibitor atirmociclib, which previously reported a 67.6% cORR in 34 patients receiving 1L atirmociclib (300mg BID) plus letrozole (link). Driven by these robust Phase 1 response rates and strong pharmacodynamic effects, BeOne is currently initiating a pivotal Phase 3 study in 1L breast cancer with FPI to happen shortly, marking a significant milestone in the drug's development pipeline.

Favorable hematologic safety profile with manageable GI toxicities. Importantly, BGB-43395 continues to demonstrate a highly differentiated safety profile compared to other CDK4 or CDK4/6 inhibitors, particularly regarding hematologic toxicities, supported by its improved CDK4/CDK6 selectivity that reduces off-target and CDK6-mediated toxicities. In the Phase 3 selected dose cohort (400mg BID), the incidence of any-grade neutropenia was only 21.2%, with notably zero grade ≥3 cases observed. BeOne did not provide the median follow up period for the safety. Although we will continue to monitor this safety profile as patient follow-up matures, this favorable tolerability already positions BGB-43395 as a strong competitive differentiator. By comparison, atirmociclib plus letrozole reported a 61.8% rate of any-grade neutropenia, with 26.5% of cases being grade ≥3 in 1L treatment (median follow up of 25 months). While there were some gastrointestinal (GI) toxicities associated with the BGB-43395 and letrozole combination, updated clinical data indicate that administration with food substantially mitigates these adverse events. Specifically, the rate of any-grade diarrhea decreased significantly from 94% to 50% following administration with food, and grade ≥3 diarrhea was completely eliminated, reducing from 6% to 0%.

Inflection point for the broader solid tumor portfolio. Beyond the promising CDK4 inhibitor data, BeOne is reaching an inflection point in its broader solid tumor pipeline, also highlighted by encouraging Phase 1 results for its GPC3/4-1BB bispecific antibody (BGB-B2033). In the 600mg Q3W monotherapy cohort for 2L+ HCC, BGB-B2033 delivered a highly compelling confirmed ORR of 36%. This efficacy is impressive when benchmarked against the frontline (1L) standard-of-care immuno-oncology combination—sintilimab plus bevacizumab (ORIENT-32 study, link) - which demonstrated a 21% ORR. Furthermore, BGB-B2033 exhibited a highly favorable safety profile, with grade ≥3 TRAEs occurring in only 8.2% of patients and minimal (1.6%) grade ≥3 AST/ALT elevations. Supported by these robust data, BeOne is planning a potentially pivotal expansion cohort for BGB-B2033 in the global 2L+ HCC setting, while studies evaluating its potential in 1L HCC are also underway.

3SBio (1530 HK)

Data Summary:

SSGJ-707 in 1L NSCLC

Updated results from the FDA-aligned pivotal dose of 10 mg/kg Q3W of a phase 2 trial (NCT06361927) evaluating SSGJ-707 (PF-08634404) monotherapy in patients with advanced NSCLC were released. Patients (pts) with treatment-naive advanced NSCLC (without actionable genomic alterations and PD-L1 TPS ≥1%) were enrolled to receive

SSGJ-707 at 5 mg/kg, 10 mg/kg, 20 mg/kg, or 30 mg/kg Q3W until disease progression or unacceptable toxicity.

As of Nov 28, 2025, 83 pts received ≥1 dose of SSGJ-707, of which 27.7% remained on treatment. In pts treated with the FDA-aligned dose of 10 mg/kg Q3W (n = 34), 41.2% remained on treatment and median duration of follow-up was 15.2 mos (95% CI, 14.3-16.2). In the 10 mg/kg group, confirmed ORR was 67.6% (95% CI, 49.5-82.6%), median DOR was not reached (NR; 95% CI, 10.9-NR), median PFS was 12.4 mos (95% CI, 8.2-NR), and median OS was NR (95% CI, 14.8-NR). High efficacy was noted for the 10 mg/kg Q3W dose irrespective of histology and TPS.

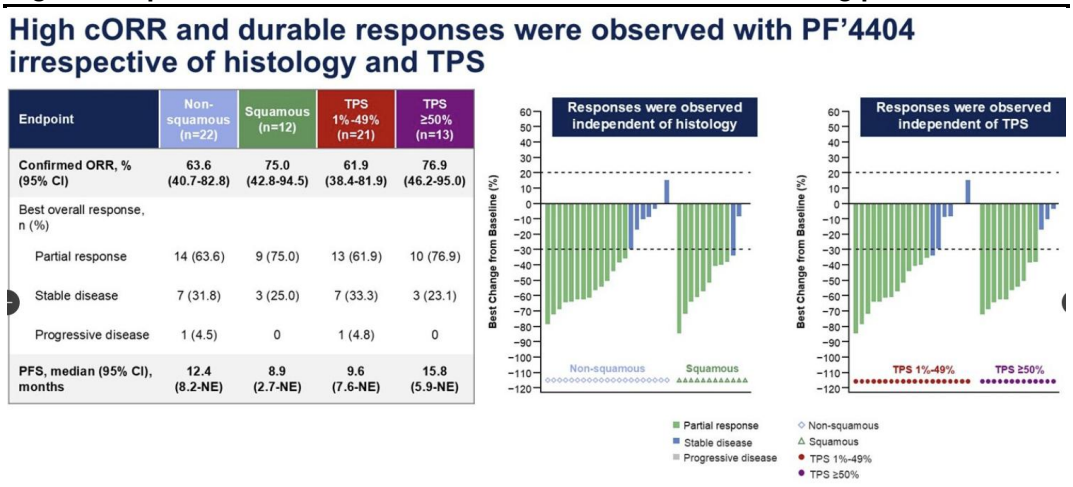
Figure 6: Summary of clinical results of SSGJ-707 in 1L PD-L1+ NSCLC

	n=34	Confirmed ORR, % (95% CI)	DOR, mos, median(95% CI)	PFS, mos, median (95% CI)	OS, mos, median(95% CI)
Histology					
SQ	12	75.0(42.8-94.5)	6.2 (4.1-NR)	8.9 (2.7-NR)	NR(4.9-NR)
NSQ	22	63.6(40.7-82.8)	NR(10.9-NR)	12.4 (8.2-NR)	NR(14.8-NR)
TPS					
1%-49%	21	61.9(38.4-81.9)	NR(4.1-NR)	9.6 (7.6-NR)	NR(12.1-NR)
≥50%	13	76.9(46.2-95.0)	NR(5.6-NR)	12.4(5.9-NR)	NR(NR-NR)

Source: 3SBio, Pfizer, CMBIGM. Note: ASCO abstract data, as of Nov 28, 2025.

Among all treated pts (n = 83), TRAEs occurred in 92.8%; grade ≥3 TRAEs occurred in 42.2%. The most common grade ≥3 TRAEs (≥5%) were pneumonia (8.4%), hypertension (7.2%), and hemoptysis (6.0%). VEGF-related AEs occurred in 62.7% (grade ≥3, 18.1%) of pts; immune-mediated AEs occurred in 37.3% (grade ≥3, 8.4%). In the 10 mg/kg group, TRAEs led to permanent discontinuation in 1 pt (2.9%) and none had grade 5 TRAE.

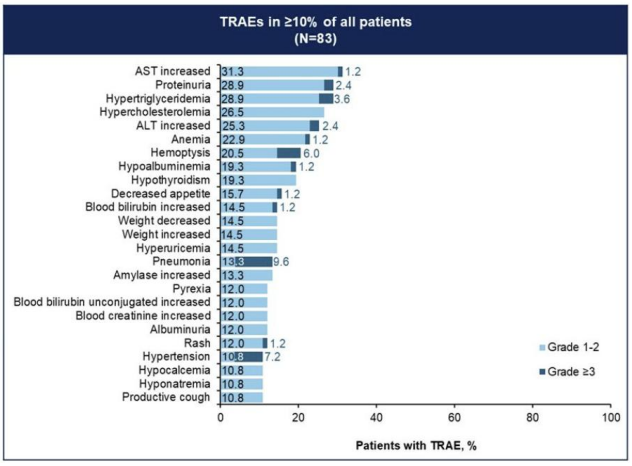
Figure 7: Updated results of SSGJ-707 in 1L PD-L1+ NSCLC during presentation



PF'4404 continues to show manageable safety and low discontinuation rate

	All patients (N=83)	10 mg/kg (n=34)
TRAEs, n (%)[a]		
Any grade	77 (92.8)	34 (100)
Grade ≥3	36 (43.4)	15 (44.1)
Grade 5	2 (2.4)[b]	0
SAE	31 (37.3)	10 (29.4)
Leading to discontinuation	7 (8.4)[c]	1 (2.9)[d]
VEGF-related AEs, n (%)[e]		
Any grade	52 (62.7)	25 (73.5)
Grade ≥3	15 (18.1)	5 (14.7)
irAEs, n (%)[f]		
Any grade	32 (38.6)	17 (50.0)
Grade ≥3	7 (8.4)	2 (5.9)[g]

AE, adverse event; ALT, alanine aminotransferase; AST, aspartate aminotransferase; irAE, immune-related adverse event; SAE, serious adverse event; TEAE, treatment-emergent adverse event; TRAE, treatment-related adverse event; VEGF, vascular endothelial growth factor.
[a]Defined as a TEAE that was "related" to PF'4404, "most possibly related" to PF'4404, or "possibly related" to PF'4404, or for which relationship to PF'4404 was missing. [b]Grade 5 TRAEs consisted of hemoptysis (n=1) and death from unknown cause (n=1). No grade 4 events occurred. [c]Hemoptysis (n=4), pneumonia (n=1), increased alanine transferase (n=1), diabetic ketoacidosis (n=1). [d]Hemoptysis [e]Defined as gastrointestinal perforation and fistula, hemorrhage, thromboembolic event, hypertension, or proteinuria. [f]Defined as any TEAE that was potentially immune mediated and categorized as "related," "most possibly related," or "possibly related" to PF'4404. [g]Abnormal hepatic function (n=1),



Source: 3SBio, Pfizer, CMBIGM. Note: ASCO presentation data

SSGJ-707 in 1L EC

Results of a phase 2 (NCT06522828) study evaluating SSGJ-707 + chemotherapy in pts with first-line (1L) advanced/recurrent endometrial cancer (EC) were released. Pts with newly diagnosed stage III/IV or recurrent EC were enrolled. Pts received SSGJ-707 5 mg/kg or 10 mg/kg Q3W + chemo (carboplatin AUC 5 + paclitaxel 175 mg/m^2) Q3W for 6 cycles, followed by SSGJ-707 maintenance tx until loss of clinical benefit or intolerable toxicity for up to 2 years. Primary endpoints were safety and ORR (RECIST 1.1).

At data cutoff (Nov 28, 2025), 32 pts with EC (26 mismatch repair proficient [pMMR], 6 MMR deficient [dMMR]) received 5 mg/kg (n=16) or 10 mg/kg (n=16) SSGJ-707 + chemo. In the evaluable population, confirmed ORR was 85.7% (12/14 pts) for the 5 mg/kg dose and 80.0% (12/15) for the 10 mg/kg dose.

Figure 8: Summary of clinical results of SSGJ-707 in 1L EC

	5 mg/kg Q3W (n=14)		10 mg/kg Q3W (n=15)	
	pMMR (n=12)	dMMR (n=2)	pMMR (n=11)	dMMR (n=4)
Confirmed ORR, n (%) [95% CI]	10 (83.3) [51.6, 97.9]	2 (100) [15.8, 100.0]	9 (81.8) [48.2, 97.7]	3 (75.0) [19.4, 99.4]
Complete response	0	0	1 (9.1)	0
Partial response	10 (83.3)	2 (100)	8 (72.7)	3 (75.0)
Stable disease	2 (16.7)	0	2 (18.2)	1 (25.0)
Progressive disease	0	0	0	0
CR/PR pending	–	–	1[a]	1
Unconfirmed ORR, n (%) [95% CI]	10 (83.3) [51.6, 97.9]	2 (100) [15.8, 100.0]	10 (90.9) [58.7, 99.8]	4 (100) [39.8, 100.0]

[a]One additional pt in the 10 mg/kg group confirmed in Dec.

Source: 3SBio, Pfizer CMBIGM. Note: ASCO abstract data, as of Nov 28, 2025.

Any-grade TRAEs were reported in 30/32 pts (93.8%) and grade ≥3 TRAEs in 22/32 pts (68.8%). The most common TRAEs (≥40%) included neutrophil count decreased (59.4%),

white blood cell count decreased (59.4%), anemia (56.3%), and platelet count decreased (56.3%). No TRAEs led to death. TRAEs led to discontinuation of SSGJ-707 in 2 pts (6.3%). Immune-related AEs occurred in 6 pts (18.8%): hypothyroidism (n=4), hyperthyroidism (n=3), and rash (n=2). VEGF-related AEs occurred in 13 pts (40.6%): blood pressure elevation (n=6), proteinuria (n=6), hemorrhage (urinary occult blood positive; n=2), perforation and fistula (n=2), and venous thrombosis (n=1).

CMBI Comments:

First mPFS readout solidified 707 as a competitive candidate in 1L PD-L1+ NSCLC. In the China Ph2 study in 1L PD-L1+ NSCLC, 707 mono (10 mg/kg Q3W) achieved mPFS of 12.4 months, slightly ahead of ivonescimab's 11.14 months reported in HARMONi-2 on a cross-trial basis. By subgroup, mPFS was 15.8 and 12.4 months in PD-L1 high and NSQ patients, respectively (vs. both of ~11 months for ivonescimab). The PFS benefits of 707 and ivonescimab in PD-L1 low subgroup are largely at the same level (see Figure below). In our view, the data support 707 as a highly competitive candidate in PD-(L)1/VEGF class. Safety profile was manageable. Gr3+ TRAEs rate was 44.1% in 10mg/kg subgroups (vs. 29.4% for ivonescimab in HARMONi-2), with Gr3+ irAEs and VEGF-related AEs were 5.9% and 14.7%, respectively.

Encouraging preliminary 1L EC data. The preliminary data for 707 + chemo in 1L EC were encouraging, especially in pMMR patients, who account for ~70% of EC and typically derive less benefits from immunotherapy. In pMMR EC, the 5mg and 10mg subgroups of 707 achieved cORRs of 83.3% and 81.8%, respectively, versus 72.3% for the current SOC of pembrolizumab + chemo on a cross-trial basis. Gr3+ TRAEs rate was 68.8% across 32 patients in both dose subgroups which was broadly manageable. Notably, Pfizer has already registered a global Phase 3 study in 1L pMMR EC.

Pfizer's strong clinical execution and further readouts should continue to be a key driver for 3Sbio. Pfizer has registered eleven global studies for 707, including three global Ph3 studies across four 1L indications. Notably, Pfizer also plans to initiate a global Ph3 trial for 707+PADCEV (Nectin-4 ADC) in 1L UC in 2026E. Looking ahead, we expect additional China Ph2 readouts of 707+chemo in 1L NSCLC and mCRC in 2H26E, which could serve as near-term catalysts.

Figure 8: Clinical data comparison of PD-(L)1/VEGF bispecific antibodies in 1L PD-L1+ NSCLC

	707	ivonescimab		BNT327 (PD-L1/VEGF)
Company	3Sbio/ Pfizer	Akeso/ Summit		BioNTech/ BMS
Phase	Ph II	Ph III		Ph I/II
Trial name	NCT06361927	NCT05499390 (HARMONi-2)		NCT05918445
N	83 (all dosage subgroups)	398		30 (NSQ: n=17 SQ: n=13)
Dosing	10 mg/kg Q3W (n=34)	Experimental: 20 mg/kg Q3W ivonescimab (n=198)	Control: Pembrolizumab (n=200)	20 mg/kg Q2W
Median follow-up	18.2 mo	8.67 mo		NSQ: 16.0 mo SQ: 8.8 mo
mPFS subgroup	**12.4 mo** PD-L1 HIGH: 15.8 mo (n=13) PD-L1 LOW: 9.6 mo (n=21) ; NSQ: 12.4 mo (n=22) SQ: 8.9 mo (n=12)	**11.14 mo, PFS HR=0.51 (P＜0.0001)** PD-L1 HIGH: ~11 mo (n=13) PD-L1 LOW: ~9 mo (n=21) ; NSQ: ~11.1 mo (n=22) SQ: ~9.7 mo (n=12)	5.82 mo	NSQ: 13.6 mo

ORR subgroup	**cORR=67.6%** PD-L1 HIGH: 76.9% (n=13) PD-L1 LOW: 61.9% (n=21) ; NSQ: 63.6% (n=22) SQ: 75.0% (n=12)	50.0%	38.5%	uORR=53.3% NSQ: uORR=47.1% (PD-L1 HIGH: uORR=50.0% (n = 8) PD-L1 LOW: uORR=44.4% (n = 9) ; SQ: uORR=61.5% (PD-L1 HIGH: uORR=71.4% (n = 7) PD-L1 LOW: uORR=50.0% (n = 6)
TRAE	100%	89.8%	81.9%	-
TRAE (Gr3+)	44.1%	29.4%	15.6%	40.0%
Reference	-	Link		Link

Source: 3Sbio, ASCO 2026, Akeso, BioNTech, CMBIGM

Figure 9: Clinical data comparison in 1L advanced/ recurrent EC

	707 (PD-1/VEGF)	Pembrolizumab (PD-1)*		HB0025 (PD-L1/VEGF)
Company	3Sbio/ Pfizer	MSD		BioNTech/ BMS
Dosing group	707 with chemo	Pembrolizumab with chemo		华奥泰
Phase	Ph II	Ph III		Ph II
Trial name	NCT06522828	NCT03914612		NCT06758557
N	32 (pMMR: n=26, dMMR: n=6)	810 (pMMR: n=588, dMMR: n=222)		39
Dosing	707 5mg/kg Q3W+paclitaxel + carboplatin: n=14 (pMMR n=12, dMMR n=2) 707 10 mg/kg Q3W+paclitaxel + carboplatin: n=15 (pMMR n=11, dMMR n=4)	Experimental: Pembrolizumab Q3W with paclitaxel + carboplatin n=404 (pMMR cohort: n=294 dMMR cohort: n=110)	Control: Placebo+paclitaxel + carboplatin n=406 (pMMR cohort: n=294 dMMR cohort: n=112)	HB0025 20mg/kg Q3W+paclitaxel + carboplatin
Median follow-up	-	Interim analysis: MMR cohort: 10.0 mo; dMMR cohort: 14.4 mo Ad Hoc analysis: MMR cohort: 20.8 mo; dMMR cohort: 22.5 mo		3.3 mo
mPFS subgroup	-	pMMR cohort: 19.5 mo (HR=0.64) dMMR cohort: NR (HR=0.45)	pMMR cohort: 11.0 mo dMMR cohort: 14.1 mo	-
ORR subgroup	**5mg/kg Q3W: cORR=85.7%** (**5mg pMMR: cORR=83.3%,** dMMR: cORR=100%) **10mg/kg Q3W: cORR=80.0%** (**10mg pMMR: cORR=81.8%** uORR=90.9%, dMMR: cORR=75.0% uORR=100%)	**pMMR cohort: ORR=72.3%** dMMR cohort: ORR=82.1%	**pMMR cohort: ORR=59.0%** dMMR cohort: ORR=71.6%	**ORR=83.9%** (**pMMR cohort: ORR=84.0%** dMMR cohort: ORR=100%)
TRAE	93.8%	96.9%	96.1%	-
TRAE (Gr3+)	68.8% (TRAE led to discontinuation in 2 pts (6.3%) , irAE: 18.8%, VEGF-related AE: 40.6%	49.9%	34.0%	46.2% (No TRAE led to treatment discontinuation or death, irAE: 5.1%)
Reference	Link	Link		Link

Source: 3Sbio, ASCO 2026, Pharmcube, CMBIGM

* mPFS results were based on interim analysis assessed by BICR, while ORRs and safety profiles were based on Ad Hoc analysis assessed by investigators.

Disclosures & Disclaimers

Analyst Certification

The research analyst who is primary responsible for the content of this research report, in whole or in part, certifies that with respect to the securities or issuer that the analyst covered in this report: (1) all of the views expressed accurately reflect his or her personal views about the subject securities or issuer; and (2) no part of his or her compensation was, is, or will be, directly or indirectly, related to the specific views expressed by that analyst in this report.
Besides, the analyst confirms that neither the analyst nor his/her associates (as defined in the code of conduct issued by The Hong Kong Securities and Futures Commission) (1) have dealt in or traded in the stock(s) covered in this research report within 30 calendar days prior to the date of issue of this report; (2) will deal in or trade in the stock(s) covered in this research report 3 business days after the date of issue of this report; (3) serve as an officer of any of the Hong Kong listed companies covered in this report; and (4) have any financial interests in the Hong Kong listed companies covered in this report.

CMBIGM Ratings

BUY	: Stock with potential return of over 15% over next 12 months
HOLD	: Stock with potential return of +15% to -10% over next 12 months
SELL	: Stock with potential loss of over 10% over next 12 months
NOT RATED	: Stock is not rated by CMBIGM
OUTPERFORM	: Industry expected to outperform the relevant broad market benchmark over next 12 months
MARKET-PERFORM	: Industry expected to perform in-line with the relevant broad market benchmark over next 12 months
UNDERPERFORM	: Industry expected to underperform the relevant broad market benchmark over next 12 months

CMB International Global Markets Limited

Address: 45/F, Champion Tower, 3 Garden Road, Hong Kong, Tel: (852) 3900 0888 Fax: (852) 3900 0800

CMB International Global Markets Limited ("CMBIGM") is a wholly owned subsidiary of CMB International Capital Corporation Limited (a wholly owned subsidiary of China Merchants Bank)

Important Disclosures

There are risks involved in transacting in any securities. The information contained in this report may not be suitable for the purposes of all investors. CMBIGM does not provide individually tailored investment advice. This report has been prepared without regard to the individual investment objectives, financial position or special requirements. Past performance has no indication of future performance, and actual events may differ materially from that which is contained in the report. The value of, and returns from, any investments are uncertain and are not guaranteed and may fluctuate as a result of their dependence on the performance of underlying assets or other variable market factors. CMBIGM recommends that investors should independently evaluate particular investments and strategies, and encourages investors to consult with a professional financial advisor in order to make their own investment decisions.
This report or any information contained herein, have been prepared by the CMBIGM, solely for the purpose of supplying information to the clients of CMBIGM or its affiliate(s) to whom it is distributed. This report is not and should not be construed as an offer or solicitation to buy or sell any security or any interest in securities or enter into any transaction. Neither CMBIGM nor any of its affiliates, shareholders, agents, consultants, directors, officers or employees shall be liable for any loss, damage or expense whatsoever, whether direct or consequential, incurred in relying on the information contained in this report. Anyone making use of the information contained in this report does so entirely at their own risk.
The information and contents contained in this report are based on the analyses and interpretations of information believed to be publicly available and reliable. CMBIGM has exerted every effort in its capacity to ensure, but not to guarantee, their accuracy, completeness, timeliness or correctness. CMBIGM provides the information, advices and forecasts on an "AS IS" basis. The information and contents are subject to change without notice. CMBIGM may issue other publications having information and/ or conclusions different from this report. These publications reflect different assumption, point-of-view and analytical methods when compiling. CMBIGM may make investment decisions or take proprietary positions that are inconsistent with the recommendations or views in this report.
CMBIGM may have a position, make markets or act as principal or engage in transactions in securities of companies referred to in this report for itself and/or on behalf of its clients from time to time. Investors should assume that CMBIGM does or seeks to have investment banking or other business relationships with the companies in this report. As a result, recipients should be aware that CMBIGM may have a conflict of interest that could affect the objectivity of this report and CMBIGM will not assume any responsibility in respect thereof. This report is for the use of intended recipients only and this publication, may not be reproduced, reprinted, sold, redistributed or published in whole or in part for any purpose without prior written consent of CMBIGM.
Additional information on recommended securities is available upon request.

For recipients of this document in the United Kingdom
This report has been provided only to persons (I)falling within Article 19(5) of the Financial Services and Markets Act 2000 (Financial Promotion) Order 2005 (as amended from time to time)("The Order") or (II) are persons falling within Article 49(2) (a) to (d) ("High Net Worth Companies, Unincorporated Associations, etc.,) of the Order, and may not be provided to any other person without the prior written consent of CMBIGM.

For recipients of this document in the United States
CMBIGM is not a registered broker-dealer in the United States. As a result, CMBIGM is not subject to U.S. rules regarding the preparation of research reports and the independence of research analysts. The research analyst who is primary responsible for the content of this research report is not registered or qualified as a research analyst with the Financial Industry Regulatory Authority ("FINRA"). The analyst is not subject to applicable restrictions under FINRA Rules intended to ensure that the analyst is not affected by potential conflicts of interest that could bear upon the reliability of the research report. This report is intended for distribution in the United States solely to "major US institutional investors", as defined in Rule 15a-6 under the US, Securities Exchange Act of 1934, as amended, and may not be furnished to any other person in the United States. Each major US institutional investor that receives a copy of this report by its acceptance hereof represents and agrees that it shall not distribute or provide this report to any other person. Any U.S. recipient of this report wishing to effect any transaction to buy or sell securities based on the information provided in this report should do so only through a U.S.-registered broker-dealer.

For recipients of this document in Singapore
This report is distributed in Singapore by CMBI (Singapore) Pte. Limited (CMBISG) (Company Regn. No. 201731928D), an Exempt Financial Adviser as defined in the Financial Advisers Act (Cap. 110) of Singapore and regulated by the Monetary Authority of Singapore. CMBISG may distribute reports produced by its respective foreign entities, affiliates or other foreign research houses pursuant to an arrangement under Regulation 32C of the Financial Advisers Regulations. Where the report is distributed in Singapore to a person who is not an Accredited Investor, Expert Investor or an Institutional Investor, as defined in the Securities and Futures Act (Cap. 289) of Singapore, CMBISG accepts legal responsibility for the contents of the report to such persons only to the extent required by law. Singapore recipients should contact CMBISG at +65 6350 4400 for matters arising from, or in connection with the report.