

Kelun-Biotech (6990 HK)

Pivotal Ph3 readouts reinforce sac-TMT's positioning in NSCLC and endometrial cancer

FLASH

Among a series of data readouts of sac-TMT (TROP2 ADC) at ESMO, we highlight two pivotal Ph3 readouts that strengthen sac-TMT's profile across NSCLC and endometrial cancer (EC). In 1L PD-L1-negative nsq-NSCLC, OptiTROP-Lung06 showed mPFS of 15.0 vs 5.7 months (HR 0.49) with lower grade ≥ 3 TEAEs and discontinuations versus chemo-IO, supporting a China NDA. Together with Lung05 in PD-L1-positive disease, these results establish activity across the PD-L1 spectrum and support sac-TMT as a differentiated IO partner to combo with both PD-1 mAb and PD-1/VEGF bsAb. In 2L+ EC, global TroFuse-005 delivered improvements in mPFS (7.2 vs 3.9 months), mOS (19.0 vs 12.1 months) and ORR (35.1% vs 17.3%), providing the first global Ph3 validation for sac-TMT. With 17 global Ph3 trials ongoing, we expect MSD to accelerate global development, with MK-2010 (PD-1/VEGF bsAb) combinations and multiple Ph3 readouts as key catalysts.

- **OptiTROP-Lung06: Compelling Ph3 readout in 1L PD-L1-negative nsq-NSCLC.** Ph3 OptiTROP-Lung06 randomized 455 patients with previously untreated advanced PD- L1-negative (TPS $<1\%$) nsq-NSCLC without sensitizing EGFR/ALK alterations to sac- TMT plus pembrolizumab (n=229) or pemetrexed/platinum plus pembrolizumab (n=226). At 9.7 months of median follow-up, BICR-assessed mPFS was 15.0 vs 5.7 months (HR 0.49; $P<0.0001$), with 12-month PFS rates of 51.1% vs 22.8%. ORR was similar (50.2% vs 47.3%), but the sac-TMT combination generated deeper responses (28.8% vs 17.3%) and longer mDoR (13.6 vs 6.8 months; HR 0.47), indicating that response durability rather than initial response drove the PFS benefit. The control arm's 5.7 months of mPFS was broadly consistent with the 6.2 months reported for PD-L1 $<1\%$ disease in KEYNOTE-189 ([link](#)). Early OS was also encouraging (HR 0.58; 95% CI 0.38–0.88), although subsequent chemotherapy use was higher in the sac-TMT arm (50.5% vs 33.3%). Grade ≥ 3 TEAEs (47.6% vs 60.6%) and TEAEs leading to discontinuation of any study drug (5.7% vs 14.2%) were lower in the sac-TMT arm, supporting the potential of sac-TMT to replace conventional chemotherapy without compromising efficacy. Stomatitis was more frequent with sac-TMT arm (51.1% vs 8.4%), but grade ≥ 3 stomatitis occurred in only 2.2% of patients; all ocular surface toxicities were grade 1–2.
- **OptiTROP-Lung05/06 support sac-TMT across the PD-L1 spectrum and pave the way for global Ph3 combinations with IO2.0.** Kelun Biotech has recently submitted a China NDA for sac-TMT plus pembrolizumab in 1L PD-L1-negative nsq-NSCLC based on OptiTROP-Lung06. In PD-L1-positive disease, Lung05 demonstrated compelling efficacy versus pembrolizumab monotherapy, with ORR of 70.2% vs 42.0% and a PFS hazard ratio of 0.35; subgroup analyses showed PFS HRs of 0.28 and 0.47 in patients with TPS 1-49% and TPS $\geq 50\%$, respectively. The China NDA for 1L PD-L1-positive NSCLC based on Lung05 was submitted in May 2026. Taken together, the Lung05/06 datasets position sac-TMT as a potentially differentiated and preferred immuno-oncology combination partner across the full PD-L1 expression spectrum in 1L NSCLC. Meanwhile, MSD is reevaluating its global 1L NSCLC strategy, with management indicating a willingness to move beyond the traditional KEYNOTE-189-style regimen and consider sac-TMT as a potential next-generation chemotherapy backbone. In this context, MSD is assessing both pembrolizumab and its PD-1/VEGF bispecific antibody MK-2010 as combination partners. Notably, the Ph2 MK-2010-003 study, evaluating MK-2010 plus sac-TMT in advanced solid tumors, was initiated in Oct 2026. MSD also plans to initiate a Ph3 study

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Target Price	HK\$642.29
Up/Downside	39.5%
Current Price	HK\$460.40

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of MK-2010 plus sac-TMT in 1L NSCLC in 1H27. In parallel, global Ph3 studies of sac-TMT combined with pembrolizumab in PD-L1 TPS $\geq 50\%$ NSCLC, squamous maintenance, and adjuvant NSCLC remain ongoing.

- **Sac-TMT sets a new benchmark in post-IO EC in its global Ph3 study.** The global TroFuse-005 Ph3 trial randomized 776 patients with 2L+ EC to sac-TMT (n=386) or physician's choice of doxorubicin/paclitaxel (TPC; n=390), all previously treated with platinum and anti-PD-(L)1 therapy and with up to three prior lines. Sac-TMT improved mPFS (7.2 vs 3.9 months; HR 0.59), mOS (19.0 vs 12.1 months; HR 0.68) and ORR (35.1% vs 17.3%). Grade ≥ 3 TRAEs were more frequent with sac-TMT (54.4% vs. 41.4%), while no new safety signals were identified. In our view, these results establish sac-TMT as a potential new standard in a setting with limited options and provide the first randomized Ph3 validation of an ADC specifically in the post-platinum/post-IO population. Competitive pressure is nevertheless emerging from B7-H4 ADCs. GSK/Hansoh's Mo-Rez reported a cORR of 67% (4.8 mg/kg; 8/12) in a small Ph1 3L+ cohort (82% with prior PD-(L)1, [link](#)). AstraZeneca's Puxi-Sam achieved a cORR of 47.1% and mPFS of 7.2 months ([link](#)). Both support further development of B7-H4 ADCs in Ph3 studies. TroFuse-005 is MSD's first global trial of Sac-TMT in the 17 ongoing global Ph3 trial to report positive results. With the NPRV, the FDA has accepted the NDA of sac-TMT in EC based on the TroFuse-005 trial with a PDUFA date of 15 Jun 2027. Additionally, in 2027, we expect further global Ph3 readouts of sac-TMT, potentially including 3L+ GC, 3L EGFRm NSCLC and HR+/HER2- LA/mBC, followed by PD-L1-high NSCLC, 2L EGFRm NSCLC and 2L CC in 2028.

Figure 1: Major Ph3 results of Sac-TMT in 1L NSCLC

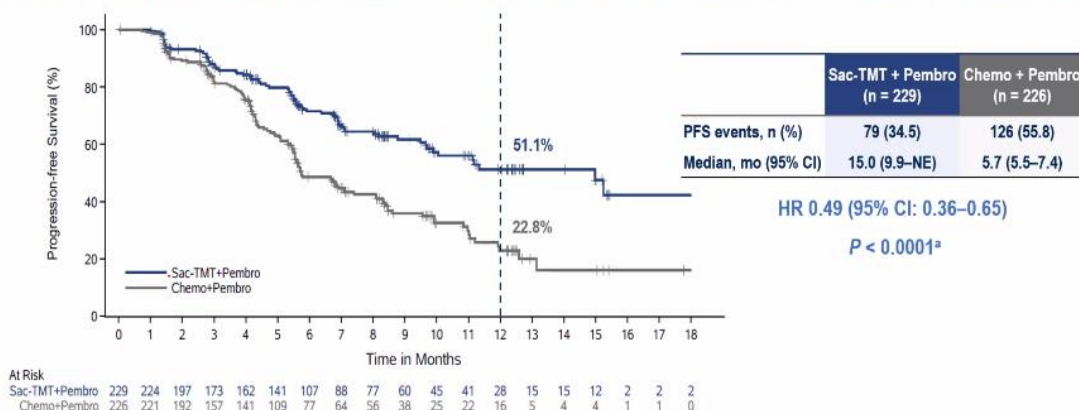
Parameter	OptiTROP-Lung05: PD-L1–positive NSCLC	OptiTROP-Lung06: PD-L1–negative NSCLC
Conference / trial ID	ASCO 2026; NCT06448312	ESMO 2026; NCT06711900
Patient population	PD-L1 TPS $\geq 1\%$; squamous and non-squamous NSCLC ; no sensitizing EGFR or ALK alterations	PD-L1 TPS $< 1\%$; non-squamous NSCLC only ; no sensitizing EGFR or ALK alterations
Sample size	413 patients: 208 combination vs 205 control	455 patients: 229 combination vs 226 control
Experimental arm	Sac-TMT 4 mg/kg Q2W + pembrolizumab 400 mg Q6W	Same as Lung05
Control arm	Pembrolizumab monotherapy	Pemetrexed + carboplatin/cisplatin + pembrolizumab
Data cutoff / median follow-up	September 29, 2025 / 10.5 months	June 9, 2026 / 9.7 months
ORR	70.2% vs 42.0% ; absolute improvement of approximately 28.3 percentage points	50.2% vs 47.3% ; broadly comparable between arms
Deep response rate	49.0% vs 25.9%	28.8% vs 17.3%
Median PFS	NR (95% CI: 13.6–NE) vs 5.7 months	15.0 months (95% CI: 9.9–NE) vs 5.7 months
PFS HR	0.35 (95% CI: 0.26–0.47); $P < 0.0001$	0.49 (95% CI: 0.36–0.65); $P < 0.0001$
12-month PFS rate	62.4% vs 29.0%	51.1% vs 22.8%
Overall survival	HR 0.55 (95% CI: 0.36–0.85); median OS: NR vs 14.5 months	HR 0.58 (95% CI: 0.38–0.88); median OS: NR in both arms
OS events	33/208 vs 54/205	36/229 vs 55/226
Duration of response	12-month DoR rate: 77.7% vs 59.4%; HR 0.47; median DoR not presented	Median DoR: 13.6 vs 6.8 months; HR 0.47
Grade ≥ 3 TEAEs	55.3% vs 31.4%	47.6% vs 60.6%
Treatment discontinuation / deaths	TEAEs leading to discontinuation of sac-TMT/pembrolizumab: 3.8%/5.3%, vs 4.9% with pembrolizumab alone; no treatment-related deaths attributed to sac-TMT	TEAEs leading to discontinuation of any study drug: 5.7% vs 14.2%; treatment-related deaths: 0.4% vs 1.3%

Source: Company data, CMBIGM

Figure 2: PFS and OS curves of OptiTROP-Lung06 in 1L PD-L1-negative NSCLC

PFS by BICR

Sac-TMT + pembro significantly improved PFS vs. Chemo + pembro, with a 51% reduction in risk of disease progression or death.



PFS by investigator assessment was consistent with the results of BICR: HR 0.52 (95% CI: 0.40–0.69).

^aUpdated efficacy boundary (corresponding to 205 actual PFS events by BICR): 0.0160 (2-sided).

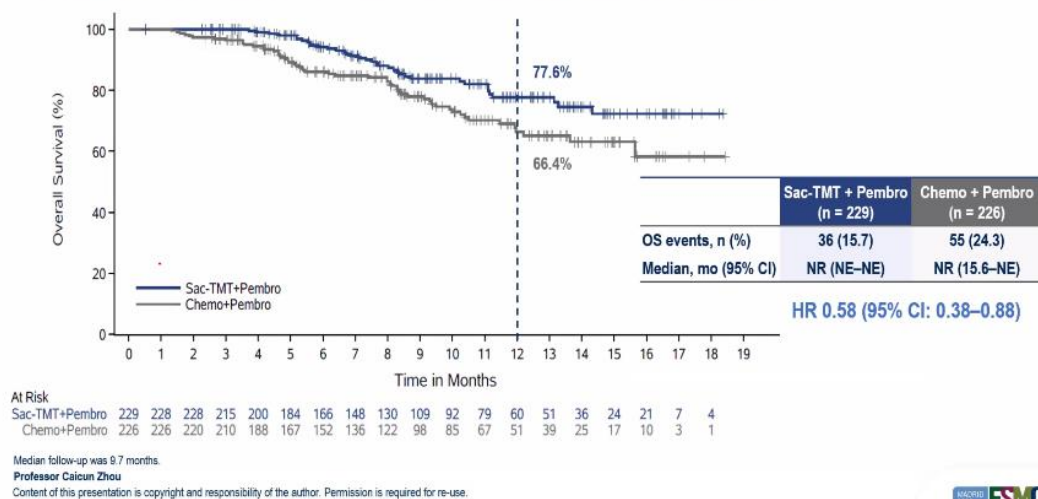
NE, not estimable.

Professor Caicun Zhou

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Descriptive Overall Survival at PFS IA

A favorable trend in overall survival was observed with sac-TMT + pembro over chemo + pembro.

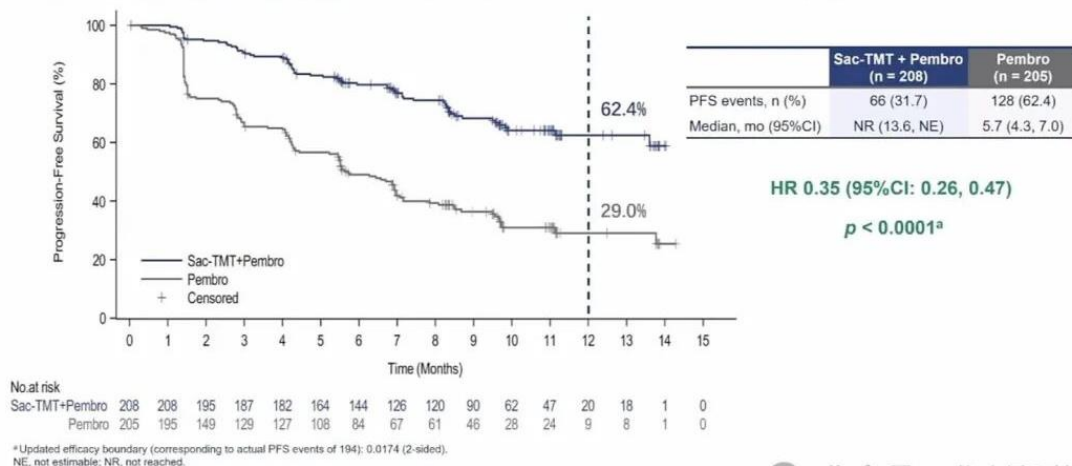


Source: Company data, ESMO, CMBIGM

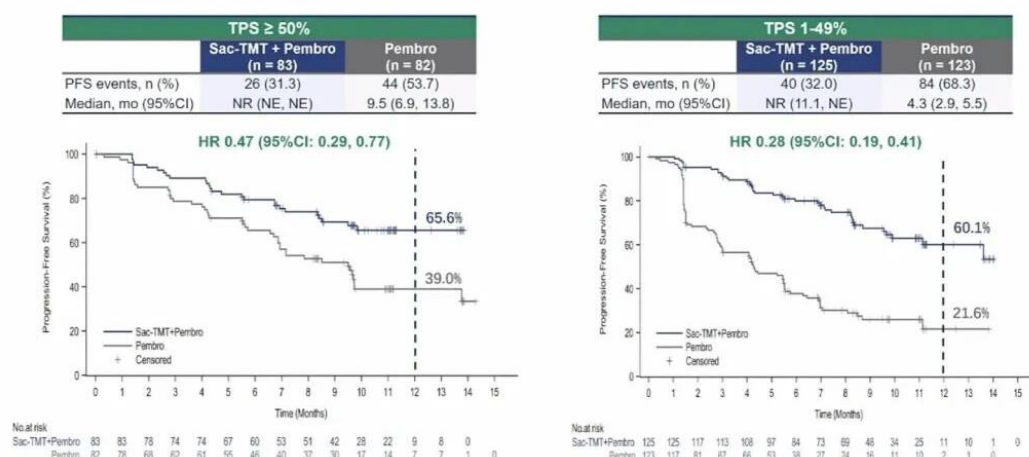
Figure 3: PFS and OS curves of OptiTROP-Lung05 in 1L PD-L1-positive NSCLC

PFS by BICR

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

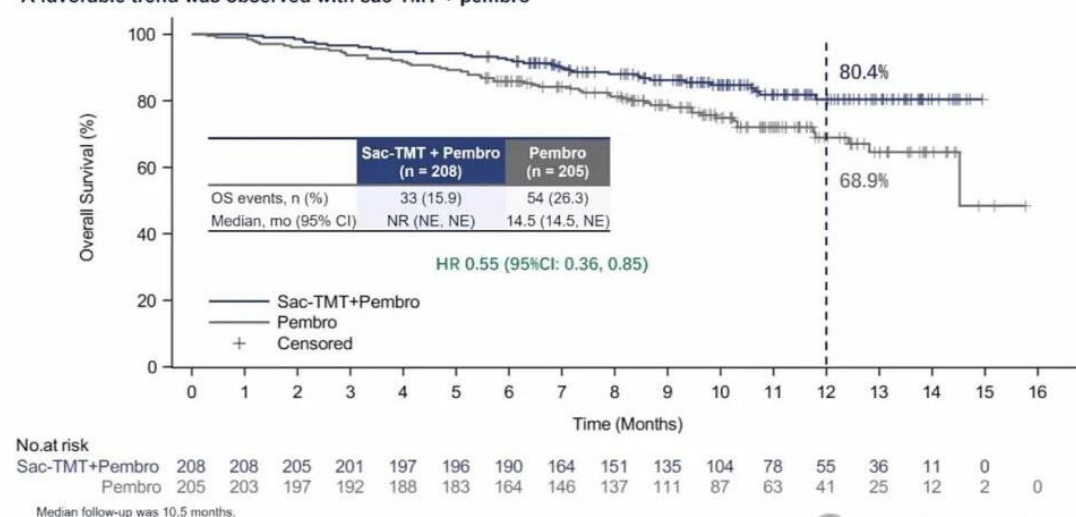


PFS (BICR) by PD-L1 Expression



Descriptive OS at PFS IA

A favorable trend was observed with sac-TMT + pembro



Source: Company data, ESMO, CMBIGM

Figure 4: Major Ph3 results of Sac-TMT in EC in global Ph3 TroFuse-005

Endpoint	Sac-TMT	TPC	Clinical interpretation
Median PFS	7.2 months	3.9 months	3.3-month improvement; HR 0.59, 41% reduction in the risk of progression or death
Median OS	19.0 months	12.1 months	6.9-month improvement; HR 0.68, 32% reduction in the risk of death
ORR	35.10%	17.30%	17.8-percentage-point improvement
Median DoR	11.1 months	6.9 months	More durable responses with sac-TMT
Responses lasting ≥6 months	69.00%	53.20%	15.8-percentage-point improvement
Responses lasting ≥12 months	42.90%	35.10%	Higher rate of durable long-term responses
Median treatment duration	31.1 weeks	15.0 weeks	Longer treatment exposure with sac-TMT
Any-grade TRAEs	97.10%	89.60%	More frequent with sac-TMT
Grade ≥3 TRAEs	54.40%	41.40%	13.0-percentage-point increase
Discontinuation due to TRAEs	3.10%	4.90%	Numerically lower with sac-TMT
Treatment-related deaths	0.80%	0.80%	Comparable between arms

Source: Company data, CMBIGM

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