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Kelun-Biotech reports Phase III success for sac-TMT combination in NSCLC

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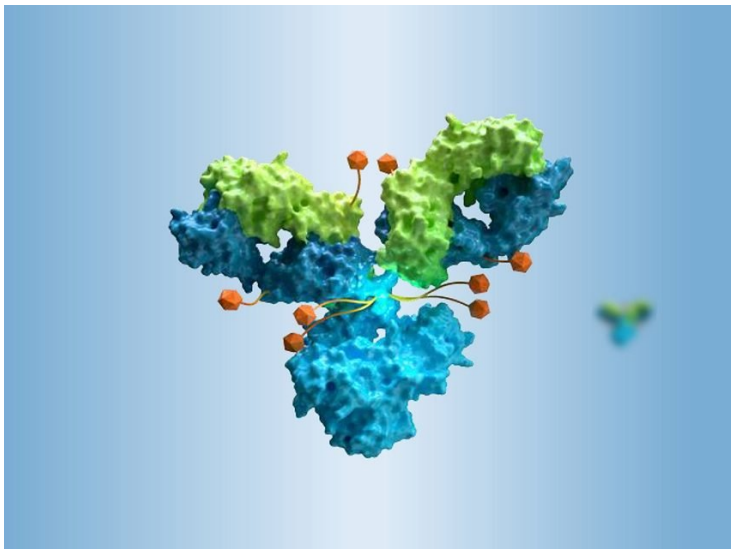
The OptiTROP-Lung06 study supports an ADC plus immunotherapy approach in first-line PD-L1-negative non-squamous lung cancer.



Kelun-Biotech has reported positive Phase III results for sacituzumab tirumotecan, also known as sac-TMT or SKB264/MK-2870, in combination with pembrolizumab as first-line treatment for PD-L1-negative non-squamous non-small cell lung cancer.

The OptiTROP-Lung06 study met its primary endpoint of progression-free survival at a prespecified interim analysis. Kelun-Biotech said the combination showed statistically significant and clinically meaningful improvement compared with pembrolizumab plus pemetrexed and platinum-based chemotherapy.

This is relevant because PD-L1-negative non-squamous NSCLC remains a difficult first-line treatment setting. Patients with low or absent PD-L1 expression may derive less benefit from immune checkpoint inhibition alone, and current standard treatment still relies heavily on chemotherapy combined with immunotherapy.

OptiTROP-Lung06 is a randomised, open-label, multicentre Phase III trial. It evaluated sac-TMT plus pembrolizumab against pembrolizumab plus pemetrexed and platinum-based chemotherapy in patients with locally advanced or metastatic non-squamous NSCLC whose tumours had PD-L1 tumour proportion score below 1 per cent.

The trial also showed a positive overall survival trend, although overall survival data were not reported as mature. The safety profile of sac-TMT plus pembrolizumab was consistent with previous studies, with no new safety signals observed.

The result is significant because Kelun-Biotech describes OptiTROP-Lung06 as the world’s first Phase III study of an antibody-drug conjugate combined with an immune checkpoint inhibitor to meet its primary endpoint in first-line driver gene-negative, PD-L1-negative non-squamous NSCLC.

Sac-TMT is a TROP2-directed antibody-drug conjugate using a belotecan-derivative topoisomerase I inhibitor payload. It is designed to recognise TROP2 on tumour cells, internalise and release the cytotoxic payload, while also supporting bystander tumour-cell killing through a membrane-permeable payload.

The combination strategy is commercially and clinically important because it aims to replace conventional chemotherapy with a targeted ADC while preserving immune checkpoint blockade. If validated through regulatory review, this could reshape treatment expectations for a population that has historically required chemotherapy-based regimens.

The positive OptiTROP-Lung06 result follows prior Phase III success in OptiTROP-Lung05, which evaluated sac-TMT plus pembrolizumab in first-line PD-L1-positive NSCLC. Together, the two trials support development of the combination across a broader first-line NSCLC population.

Sac-TMT is already approved and marketed in China across multiple indications, including triple-negative breast cancer and several NSCLC settings. It has also been licensed to MSD outside Greater China, and MSD has initiated multiple global Phase III studies involving sac-TMT as monotherapy or in combination with pembrolizumab.