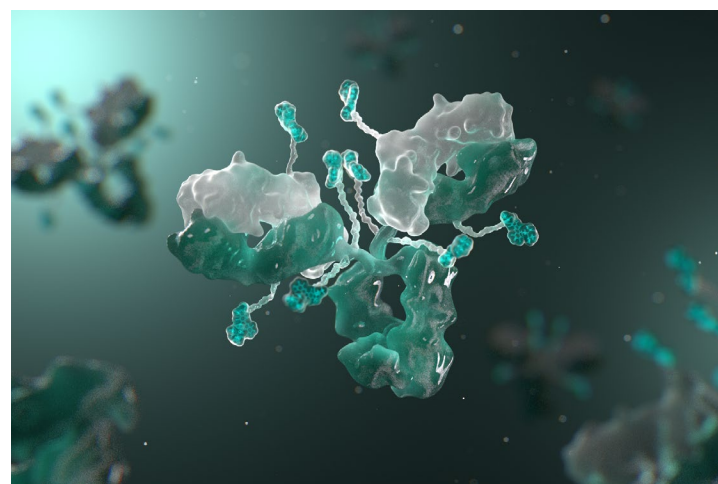


# Sacituzumab Tirumotecan (Sac-TMT) TroFuse Phase 3 Clinical Development Program



## Exploring the potential of sac-TMT across multiple cancer types

*A cornerstone of Merck's ADC portfolio spanning early-to-late-stage disease*

Sac-TMT is an investigational TROP2-directed ADC with a belotecan-derived topoisomerase I inhibitor payload and a bifunctional linker designed with the potential to maximize payload delivery to tumor cells and minimize payload loss while circulating in the body. Sac-TMT is the only TROP2 ADC designed with a focus on both ends of the linker.

TROP2 is overexpressed on tumor cells compared to healthy cells in many common cancers, and through the TroFuse clinical development program, Merck is evaluating sac-TMT in 17 ongoing global Phase 3 trials across multiple tumor types, the broadest range of disease and treatment settings compared to any TROP2-directed ADC to date. The TroFuse development program spans early-to-late-stage disease in more than nine disease areas and includes more than 15,000 patients worldwide. Numerous Phase 3 trials are exploring sac-TMT as monotherapy and in combination with immunotherapies, aiming to improve survival and quality of life for patients with advanced and earlier-stage cancers.



### GYNECOLOGIC CANCERS

	Study Description	Primary Endpoints	Estimated Enrollment	Estimated Primary Completion Date
Endometrial	<b>TroFuse-005</b> NCT06132958 <a href="#">🔗</a> Comparing the Efficacy and Safety of sac-TMT Monotherapy Versus TPC in Participants With Endometrial Cancer Who Have Received Prior Platinum-based Chemotherapy and Immunotherapy	<ul style="list-style-type: none"> <li>• PFS</li> <li>• OS</li> <li>• Safety</li> </ul>	710	January 2028
	<b>TroFuse-033</b> NCT06952504 <a href="#">🔗</a> Comparing the Efficacy and Safety of sac-TMT in Combination With Pembrolizumab Versus Pembrolizumab Alone as 1L Maintenance Treatment in Participants With Mismatch Repair Proficient Endometrial Cancer	<ul style="list-style-type: none"> <li>• PFS</li> <li>• OS</li> <li>• Safety</li> </ul>	1,123	May 2032
Ovarian	<b>TroFuse-021</b> NCT07318558 <a href="#">🔗</a> Comparing sac-TMT Maintenance Treatment With or Without Bevacizumab Versus SOC in Participants With Newly Diagnosed Advanced Non-HRD Positive Ovarian Cancer	<ul style="list-style-type: none"> <li>• PFS</li> <li>• Safety</li> </ul>	900	February 2033
	<b>TroFuse-022</b> NCT06824467 <a href="#">🔗</a> Evaluating the Efficacy and Safety of sac-TMT Maintenance Treatment With or Without Bevacizumab Versus SOC After 2L Platinum-based Doublet Chemotherapy in Participants With Platinum-sensitive Recurrent Ovarian Cancer	<ul style="list-style-type: none"> <li>• PFS</li> <li>• Safety</li> </ul>	770	April 2029
Cervical	<b>TroFuse-020</b> NCT06459180 <a href="#">🔗</a> Comparing the Efficacy and Safety of sac-TMT Monotherapy Versus TPC as 2L Treatment for Participants With Recurrent or Metastatic Cervical Cancer	<ul style="list-style-type: none"> <li>• ORR</li> <li>• OS</li> <li>• Safety</li> </ul>	686	June 2028
	<b>TroFuse-036</b> NCT07216703 <a href="#">🔗</a> Evaluating the Efficacy and Safety of sac-TMT in Combination With Pembrolizumab With or Without Bevacizumab Compared With SOC as 1L Maintenance Treatment for Participants With Persistent, Recurrent or Newly Diagnosed Metastatic Cervical Cancer With PD-L1 CPS ≥ 1	<ul style="list-style-type: none"> <li>• PFS</li> <li>• OS</li> <li>• Safety</li> </ul>	1,023	October 2031

### BREAST CANCERS

	Study Description	Primary Endpoints	Estimated Enrollment	Estimated Primary Completion Date
	<b>TroFuse-010</b> NCT06312176 <a href="#">🔗</a> Comparing sac-TMT as a Single Agent and in Combination With Pembrolizumab Versus TPC in Participants With HR+/HER2- Unresectable Locally Advanced or Metastatic Breast Cancer	<ul style="list-style-type: none"> <li>• PFS</li> <li>• Safety</li> </ul>	1,200	July 2027
	<b>TroFuse-011</b> NCT06841354 <a href="#">🔗</a> Comparing Efficacy and Safety of sac-TMT as a Monotherapy and in Combination With Pembrolizumab Versus TPC in Participants With Previously Untreated Locally Recurrent Unresectable or Metastatic TNBC Expressing PD-L1 at CPS < 10	<ul style="list-style-type: none"> <li>• PFS</li> <li>• OS</li> <li>• Safety</li> </ul>	1,000	May 2030
	<b>TroFuse-012</b> NCT06393374 <a href="#">🔗</a> Comparing the Efficacy and Safety of Adjuvant sac-TMT in Combination With Pembrolizumab Versus TPC in Participants With TNBC Who Received Neoadjuvant Therapy and Did Not Achieve a pCR at Surgery	<ul style="list-style-type: none"> <li>• iDFS</li> <li>• Safety</li> </ul>	1,530	December 2030
	<b>TroFuse-032</b> NCT06966700 <a href="#">🔗</a> Evaluating the Efficacy and Safety of sac-TMT Followed by Carboplatin/Paclitaxel Versus Chemotherapy, Both in Combination With Pembrolizumab as Neoadjuvant Therapy for High-Risk, Early-Stage, TNBC or HR+/HER2- Breast Cancer	<ul style="list-style-type: none"> <li>• pCR</li> <li>• EFS</li> <li>• Safety</li> </ul>	2,400	March 2033

### LUNG CANCERS

	Study Description	Primary Endpoints	Estimated Enrollment	Estimated Primary Completion Date
	<b>TroFuse-004</b> NCT06074588 <a href="#">🔗</a> Comparing sac-TMT Versus Chemotherapy (Docetaxel or Pemetrexed) in Previously Treated Advanced or Metastatic NSCLC With EGFR Mutations or Other Genomic Alterations	<ul style="list-style-type: none"> <li>• PFS</li> <li>• OS</li> <li>• Safety</li> </ul>	556	May 2027
	<b>TroFuse-007</b> NCT06170788 <a href="#">🔗</a> Comparing sac-TMT in Combination With Pembrolizumab Compared to Pembrolizumab Monotherapy in the 1L Treatment of Participants With Metastatic NSCLC With PD-L1 TPS ≥ 50%	<ul style="list-style-type: none"> <li>• OS</li> <li>• Safety</li> </ul>	614	January 2028
	<b>TroFuse-009</b> NCT06305754 <a href="#">🔗</a> Comparing sac-TMT Versus Platinum Doublets in Participants With EGFR-mutated, Advanced Nonsquamous NSCLC Who Have Progressed on Prior EGFR Tyrosine Kinase Inhibitors	<ul style="list-style-type: none"> <li>• PFS</li> <li>• OS</li> <li>• Safety</li> </ul>	520	September 2028
	<b>TroFuse-019</b> NCT06312137 <a href="#">🔗</a> Comparing Adjuvant Pembrolizumab With or Without sac-TMT in Participants With Resectable Stage II to IIIB (N2) NSCLC Not Achieving pCR After Receiving Neoadjuvant Pembrolizumab With Platinum-based Doublet Chemotherapy	<ul style="list-style-type: none"> <li>• DFS</li> <li>• Safety</li> </ul>	780	February 2034
	<b>TroFuse-023</b> NCT06422143 <a href="#">🔗</a> Comparing Pembrolizumab in Combination With Carboplatin/Taxane (Paclitaxel or Nab-paclitaxel) Followed by Pembrolizumab With or Without Maintenance sac-TMT in the 1L Treatment of Metastatic Squamous NSCLC	<ul style="list-style-type: none"> <li>• OS</li> <li>• Safety</li> </ul>	851	January 2029

### GASTROINTESTINAL AND GENITOURINARY CANCERS

	Study Description	Primary Endpoints	Estimated Enrollment	Estimated Primary Completion Date
	<b>TroFuse-015</b> NCT06356311 <a href="#">🔗</a> Comparing the Efficacy and Safety of sac-TMT Versus TPC in 3L+ Advanced/Metastatic Gastroesophageal Adenocarcinoma	<ul style="list-style-type: none"> <li>• OS</li> <li>• Safety</li> </ul>	450	January 2027
	<b>TroFuse-031</b> NCT07419295 <a href="#">🔗</a> Comparing sac-TMT Versus Investigator's Choice of Non-platinum Chemotherapy in Participants With Pretreated Locally Advanced/Metastatic Urothelial Carcinoma	<ul style="list-style-type: none"> <li>• OS</li> <li>• Safety</li> </ul>	590	July 2029

### Abbreviations

<b>1L</b> first-line	<b>2L</b> second-line	<b>3L</b> third-line	<b>ADC</b> antibody-drug conjugate	<b>CPS</b> combined positive score
<b>DFS</b> disease-free survival	<b>EFS</b> event-free survival	<b>EGFR</b> epidermal growth factor receptor	<b>HR+/HER2-</b> hormone receptor-low positive/human epidermal growth factor receptor-2 negative	<b>HRD</b> homologous recombination deficiency
<b>iDFS</b> invasive disease-free survival	<b>NSCLC</b> non-small cell lung cancer	<b>ORR</b> objective response rate	<b>OS</b> overall survival	<b>pCR</b> pathological complete response
<b>PD-L1</b> programmed death-ligand 1	<b>PFS</b> progression-free survival	<b>sac-TMT</b> sacituzumab tirumotecan	<b>SOC</b> standard of care	<b>TNBC</b> triple-negative breast cancer
<b>TPC</b> treatment of physician's choice	<b>TPS</b> tumor proportion score	<b>TROP2</b> trophoblast cell surface antigen 2		

Sac-TMT was developed by Kelun-Biotech. Under a collaboration agreement, Kelun-Biotech has granted Merck the exclusive rights to develop, manufacture and commercialize sac-TMT in all territories outside of Greater China (which includes Mainland China, Hong Kong, Macau and Taiwan). Our strategic partnership with Kelun-Biotech harnesses advanced ADC technology and enriches Merck's oncology pipeline with novel linker and payload platforms to develop multiple tissue-targeted therapies across diverse tumor types.