NEWS RELEASE

Merck Announces TroFuse-015 Trial Evaluating Sacituzumab Tirumotecan (Sac-TMT) Met Primary Endpoint of Overall Survival (OS) in Third-Line or Later Locally Advanced Unresectable or Metastatic Gastroesophageal Adenocarcinoma

2026-11-20

Sac-TMT is the first TROP2 ADC to improve OS compared to treatment of physician's choice (TPC) in patients with advanced gastroesophageal adenocarcinoma who have received two or more prior lines of systemic therapy in a global Phase 3 study

TroFuse-015 is the second positive Phase 3 readout from the global TroFuse clinical development program evaluating sac-TMT across multiple tumor types

RAHWAY, N.J.--(BUSINESS WIRE)-- Merck (NYSE: MRK), known as MSD outside of the United States and Canada, today announced the pivotal Phase 3 TroFuse-015 trial evaluating sacituzumab tirumotecan (sac-TMT), an investigational TROP2-directed antibody-drug conjugate (ADC) licensed from Kelun-Biotech, met its primary endpoint of overall survival (OS) compared to treatment of physician's choice (TPC, consisting of trifluridine-tipiracil, irinotecan, paclitaxel or docetaxel) in the treatment of patients with locally advanced unresectable or metastatic gastroesophageal adenocarcinoma who have received two or more prior lines of systemic therapy. TroFuse-015 represents the first time a TROP2-directed ADC has demonstrated an OS benefit in a global Phase 3 trial in this patient population, where there is significant unmet need. These data will be presented at an upcoming medical meeting and shared with regulatory authorities.

At final analysis, sac-TMT demonstrated a statistically significant and clinically meaningful improvement in OS compared to TPC for these patients who have received two or more prior lines of systemic therapy. Results were generally consistent across subgroups regardless of TROP2 expression status. Sac-TMT did not meet the secondary endpoint of progression-free survival (PFS) assessed by blinded independent central review (BICR). Additionally, sac-TMT showed a nominally improved benefit in objective response rate (ORR), a secondary endpoint, favoring sac-TMT compared with TPC, but this was not formally tested under the prespecified analysis plan. The safety profile was consistent with what has been observed in previously reported studies of sac-TMT; no new safety signals were observed.

"Sac-TMT is the first TROP2 ADC to improve OS in a global Phase 3 study in advanced gastroesophageal adenocarcinoma compared to TPC, demonstrating its potential in a particularly challenging disease setting," said Dr. Marjorie Green, senior vice president and head of oncology, global clinical development, Merck Research Laboratories. "There is a tremendous unmet need for therapies that can improve survival for these patients. We look forward to discussing these data with regulatory authorities and sharing with the scientific community on behalf of patients who may benefit."

TroFuse-015 also marks the second positive Phase 3 study from Merck's **TroFuse clinical development program** for sac-TMT. The program currently consists of 18 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 program is evaluating sac-TMT across a diverse range of tumor types, including endometrial, bladder, breast, cervical, gastric, non-small cell lung and ovarian cancers, and it spans early-to-late-stage disease as both monotherapy and in combination with immunotherapies. Within the program, 14 of the 18 Phase 3 studies are pursuing first-in-class opportunities to address unmet medical needs, including TroFuse-015.

About TroFuse-015

TroFuse-015 is a randomized, open-label, multicenter, global Phase 3 trial (ClinicalTrials.gov, **NCT06356311**) evaluating the efficacy and safety of the TROP2-directed antibody-drug conjugate sacituzumab tirumotecan (sac-TMT) compared to the treatment of physician's choice (TPC) in participants with locally advanced unresectable or metastatic gastroesophageal adenocarcinoma who have received two or more prior lines of systemic therapy. The trial enrolled 473 patients who were randomized to receive either sac-TMT or TPC, consisting of trifluridine-tipiracil, irinotecan, paclitaxel or docetaxel. Sac-TMT (4 mg/kg) was administered on Days 1, 15 and 29 of each six-week treatment cycle. Trifluridine-tipiracil (35 mg/m^2) was administered orally twice daily on Days 1-5 and 8-12 of each four-week treatment cycle. Irinotecan (150 mg/m^2) was administered on Days 1 and 15 of each four-week treatment cycle. Paclitaxel (80 mg/m^2) was administered on Days 1, 8 and 15 of each four-week treatment cycle. Docetaxel (75 mg/m^2) was administered on Day 1 of each three-week treatment cycle.

The study has a primary endpoint of overall survival. Secondary endpoints include progression-free survival, objective response rate, and duration of response.

About sacituzumab tirumotecan (sac-TMT)

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

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 18 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.

About Gastroesophageal Adenocarcinoma

Gastroesophageal adenocarcinoma comprises gastric, gastroesophageal junction (GEJ), and esophageal adenocarcinomas (EAC).

Gastric (stomach) cancer often does not cause symptoms in its early stages, making it difficult to detect before the disease has advanced. Most gastric cancers are adenocarcinomas, accounting for approximately 90% to 95% of gastric malignancies, which develop from cells in the innermost lining of the stomach, known as the mucosa. In the U.S., it is estimated there will be approximately 31,500 new cases of gastric cancer and 10,700 deaths from the disease in 2026. Gastric cancer accounts for approximately 1.5% of all new cancers diagnosed in the U.S. each year.

Esophageal cancer starts when cells in the lining of the esophagus begin to grow out of control. In the U.S., about 68% of all new cases of esophageal cancer are EAC, and it is estimated there will be more than 14,300 new cases of EAC in 2026. Approximately 42% of EAC patients in the U.S. are diagnosed at the distant disease stage.

About the Merck and Kelun-Biotech Agreement

Sac-TMT was developed by Kelun-Biotech. Kelun-Biotech (6990.HK) is a holding subsidiary of Kelun Pharmaceutical (002422.SZ), which focuses on the R&D, manufacturing, commercialization and global collaboration of innovative biological drugs and small molecule drugs. Under an exclusive license and 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).

Merck's focus on cancer

Every day, we follow the science as we work to discover innovations that can help patients, no matter what stage of cancer they have. As a leading oncology company, we are pursuing research where scientific opportunity and medical need converge, underpinned by our diverse pipeline of more than 20 novel mechanisms. With one of the largest clinical development programs across more than 25 tumor types, we strive to advance breakthrough science that will shape the future of oncology. By addressing barriers to clinical trial participation, screening and treatment, we work with urgency to reduce disparities and help ensure patients have access to high-quality cancer care. Our unwavering commitment is what will bring us closer to our goal of bringing life to more patients with cancer. For more information, visit **https://www.merck.com/research/oncology**.

About Merck

At Merck, known as MSD outside of the United States and Canada, we are unified around our purpose: We use the power of leading-edge science to save and improve lives around the world. For more than 130 years, we have brought hope to humanity through the development of important medicines and vaccines. We aspire to be the premier research-intensive biopharmaceutical company in the world – and today, we are at the forefront of research to deliver innovative health solutions that advance the prevention and treatment of diseases in people and animals. We foster a diverse and inclusive global workforce and operate responsibly every day to enable a safe, sustainable and healthy future for all people and communities. For more information, visit **www.merck.com** and connect with us on **X (formerly Twitter)**, **Facebook**, **Instagram**, **YouTube** and **LinkedIn**.

Forward-Looking Statement of Merck & Co., Inc., Rahway, N.J., USA

This news release of Merck & Co., Inc., Rahway, N.J., USA (the "company") includes "forward-looking statements" within the meaning of the safe harbor provisions of the U.S. Private Securities Litigation Reform Act of 1995. These statements are based upon the current beliefs and expectations of the company's management and are subject to significant risks and uncertainties. There can be no guarantees with respect to pipeline candidates that the candidates will receive the necessary regulatory approvals or that they will prove to be commercially successful. If underlying assumptions prove inaccurate or risks or uncertainties materialize, actual results may differ materially from those set forth in the forward-looking statements.

Risks and uncertainties include but are not limited to, general industry conditions and competition; general economic factors, including interest rate and currency exchange rate fluctuations; the impact of pharmaceutical industry regulation and health care legislation in the United States and internationally; global trends toward health care cost containment; technological advances, new products and patents attained by competitors; challenges inherent in new product development, including obtaining regulatory approval; the company's ability to accurately predict future market conditions; manufacturing difficulties or delays; financial instability of international economies and sovereign risk; dependence on the effectiveness of the company's patents and other protections for

innovative products; and the exposure to litigation, including patent litigation, and/or regulatory actions.

The company undertakes no obligation to publicly update any forward-looking statement, whether as a result of new information, future events or otherwise. Additional factors that could cause results to differ materially from those described in the forward-looking statements can be found in the company's Annual Report on Form 10-K for the year ended December 31, 2025, and the company's other filings with the Securities and Exchange Commission (SEC) available at the SEC's Internet site (**www.sec.gov**).

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Source: Merck & Co., Inc.