NEWS RELEASE

Merck Announces TroFuse-005 Trial Evaluating Sacituzumab Tirumotecan (Sac-TMT) Met Primary Endpoints of Overall Survival (OS) and Progression-Free Survival (PFS) in Certain Patients With Advanced or Recurrent Endometrial Cancer

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Sac-TMT is the first TROP2 ADC to improve OS and PFS compared to chemotherapy in patients with advanced or recurrent endometrial cancer who have progressed after platinum-based chemotherapy and anti-PD-1/L1 immunotherapy in a global Phase 3 study

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-005 trial evaluating sacituzumab tirumotecan (sac-TMT), an investigational TROP2-directed antibody-drug conjugate (ADC) being developed in collaboration with Kelun-Biotech, met its primary endpoints of overall survival (OS) and progression-free survival (PFS) in certain patients with advanced or recurrent endometrial cancer. TroFuse-005 is the first global Phase 3 trial to demonstrate statistically significant improvement in both OS and PFS compared to chemotherapy for these patients and the first and only ADC to do so for patients with endometrial cancer in this setting.

At a pre-specified interim analysis, sac-TMT demonstrated a statistically significant and clinically meaningful improvement in OS and PFS compared to treatment of physician’s choice (TPC, consisting of doxorubicin or paclitaxel) for patients with endometrial cancer who have previously received platinum-based chemotherapy and anti-PD-1/L1 immunotherapy either together or separately. The study also reached its key secondary endpoint of objective response rate. These data will be presented at an upcoming medical meeting and discussed with

regulatory authorities worldwide.

The safety profile was consistent with what has been observed in previously reported studies of sac-TMT; no new safety signals were observed.

“These results show sac-TMT may be able to address a critical unmet need for certain patients with advanced endometrial cancer, one of the only cancers increasing in both incidence and mortality worldwide,” said Dr. Domenica Lorusso, the study’s global lead investigator, lead investigator for ENGOT and professor of Obstetrics and Gynecology at Humanitas University and Humanitas San Pio X, Milan. “Despite recent advances, patients whose disease progresses following treatment with platinum and immunotherapy are urgently in need of new options, and these findings show for the first time that a TROP2 ADC may be an effective option in this setting.”

“The scale and ambition of our expansive TroFuse program reflects our deep commitment to advancing one of the industry’s leading ADC pipelines to make a difference for more people facing cancer and builds on our legacy of leadership in gynecologic cancer research,” said Dr. Dean Y. Li, president, Merck Research Laboratories. “These findings reinforce our belief that sac-TMT, with its proprietary bifunctional linker designed with the intent to maximize payload delivery to tumors while minimizing impact on healthy cells in the body, has the potential to become a cornerstone in the treatment of certain patients with advanced endometrial cancer. We thank the patients and investigators for participating in our studies as well as our collaborators at Kelun-Biotech for helping us advance this important treatment.”

TroFuse-005 also marks the first positive Phase 3 results from Merck’s **TroFuse clinical development program** for sac-TMT. The program currently consists of 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, including 10 Phase 3 trials in women’s cancers. 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. This includes the ongoing TroFuse-033 trial in first line mismatch repair proficient endometrial cancer.

About TroFuse-005

TroFuse-005 is a randomized, active-controlled, open-label, multicenter, global Phase 3 trial (ClinicalTrials.gov, **NCT06132958**) evaluating sac-TMT versus TPC in patients with endometrial carcinoma and carcinosarcoma who have received prior platinum-based chemotherapy and anti-PD-1/anti-PD-L1 immunotherapy either together or separately. The trial enrolled 776 patients who were randomized to receive either sac-TMT or TPC, consisting of doxorubicin or paclitaxel. Sac-TMT (4 mg/kg) was administered on Day 1 of each two-week treatment cycle. Doxorubicin (60 mg/m^2) was administered on Day 1 of each three-week treatment cycle and paclitaxel (80 mg/m^2)

was administered on Days 1, 8 and 15 of each four-week treatment cycle.

The study has dual primary endpoints: PFS by blinded independent central review (BICR), defined as the time from randomization to the first documented disease progression or death from any cause, and OS, defined as the time from randomization to death from any cause. A key secondary endpoint is objective response rate, and other secondary endpoints include duration of response, incidence of adverse events, treatment discontinuation due to adverse events and change from baseline in global health status/quality-of-life scores.

About sacituzumab tirumotecan (sac-TMT)

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.

About endometrial cancer

Endometrial cancer (also referred to as endometrial carcinoma) begins in the inner lining of the uterus, which is known as the endometrium, and is the most common type of cancer in the uterus. More than 90% of uterine body cancers occur in the endometrium. In the U.S., it is estimated there will be approximately 68,270 patients diagnosed with endometrial cancer and approximately 14,450 patient deaths from the disease in 2026. Globally, endometrial cancer is the sixth most common cancer in women and the 15th most common cancer overall. Following primary treatment, patients face a risk of their cancer returning, often as distant metastasis, which is associated with poorer outcomes.

About Merck’s research in women’s cancers

Merck is advancing research aimed at expanding treatment options for certain breast and gynecologic (ovarian, cervical and endometrial) cancers, with a goal of improving outcomes for more patients affected by these diseases. Breast cancer and gynecologic cancers are the first and second most commonly occurring cancer types among

women worldwide, respectively, and Merck aims to provide options to patients facing these devastating diseases. With more than 20 clinical trials in nearly 20,000 patients around the world, Merck is driving innovative research to purposefully advance standards of care in women's cancers. Merck's research efforts include trials focused on evaluating its medicines in earlier stages, as well as identifying novel mechanisms and new combinations with these treatments. Through our portfolio and pipeline, Merck is working to address the impact of women's cancers on patients, their families and communities globally.

About the Merck and Kelun-Biotech strategic collaboration

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 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).

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 25 novel mechanisms. With one of the largest clinical development programs across more than 30 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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