



## News Release

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### **Not intended for UK-based media**

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## **Merck KGaA, Darmstadt, Germany, Announces First Patient Dosed in Phase 3 Study for Investigational Antibody-Drug Conjugate in Colorectal Cancer**

- **Precectabart tocentecan (Precem-TcT) is investigated as a potential first-in-class anti-CEACAM5 ADC, for the treatment of metastatic CRC (mCRC)**
- **CEACAM5 is overexpressed in the majority of colorectal tumors (~90%), and requires no patient selection**
- **Significant unmet need remains for clinically meaningful innovation in colorectal cancer (CRC), the second leading cause of cancer death worldwide**

DARMSTADT, Germany, May 21, 2026 – Merck KGaA, Darmstadt, Germany, a leading science and technology company, today announced that the first patient has been dosed in the Phase 3 PROCEADE<sup>®</sup>-CRC-03 trial ([NCT07549412](https://clinicaltrials.gov/ct2/show/study/NCT07549412)). The study is evaluating precectabart tocentecan (Precem-TcT), a potential first-in-class investigational anti-CEACAM5 antibody-drug conjugate (ADC), for the treatment of metastatic colorectal cancer (mCRC).

“Leveraging our novel payload-linker technology, Precem-TcT is the first CEACAM5-targeted ADC in clinical studies with an exatecan payload, rationally designed for stability and enhanced cancer cell killing activity,” said David Weinreich, MD, MBA, Global Head of R&D and Chief Medical Officer, Merck KGaA, Darmstadt, Germany. “The Phase 3 study and the enrollment of the first patient





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with Precem-TcT build on the Company's more than 20 years of expertise in colorectal cancer, and highlight our commitment to advancing differentiated ADCs for heavily pretreated patients with limited treatment options."

The PROCEADE<sup>®</sup>-CRC-03 study assesses the efficacy and safety of Precem-TcT, alone or with bevacizumab, in patients with mCRC who are intolerant- or refractory-to, or progressed after, systemic therapies. The PROCEADE<sup>®</sup>-CRC-03 study will be conducted in approximately 165 sites in 20 countries and will recruit approximately 1,020 patients with mCRC.

In Phase 1 (PROCEADE<sup>®</sup>-CRC-01; [NCT05464030](#)), Precem-TcT as monotherapy or in combination showed predictable and manageable safety in more than 100 patients with heavily pretreated mCRC. At the recommended dose for Phase 3 development (2.8 mg/kg Q3W; n=29), confirmed objective response rate (cORR) was 20.7% (95% CI: 8.0, 39.7), median PFS was 6.9 months (95% CI: 4.4, 9.5) and median OS was not reached (95% CI: 8.7, NE) after a median follow-up of 13.1 months.

"The PROCEADE<sup>®</sup>-CRC-03 Phase 3 study is designed to address significant unmet needs for patients with metastatic colon cancer whose disease has progressed after standard therapies," said Kanwal P.S. Raghav, MBSS, MD, Department of Gastrointestinal Medical Oncology, MD Anderson Cancer Center, Houston. "The data from the phase 1 study suggested a manageable safety profile for Precem-TcT and encouraging early tumor response in the patients with heavily pre-treated metastatic colorectal cancer. CEACAM5 is largely absent from healthy tissues and is overexpressed in nearly all mCRC cases, supporting a non-selective, universal patient approach, and represents a promising therapeutic target in this setting."

Globally, CRC is the third-most commonly diagnosed malignancy and the second leading cause of cancer-related deaths.<sup>1</sup> Merck KGaA, Darmstadt, Germany, chose mCRC as the first indication to assess the efficacy and safety of Precem-TcT because ~90% of colorectal cancers overexpress CEACAM5,<sup>2</sup> and there is a high unmet clinical need in patients with metastatic colorectal cancer, especially among those who progressed on several previous therapies.<sup>3,4,5</sup> Patients with advanced colorectal cancer typically face a challenging prognosis, with few options available for those



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whose disease continues to progress after three or more lines of therapy. Additionally, with progression, response to treatment and prognosis become increasingly worse over time.

### **Advancing the Future of Cancer Care**

At Merck KGaA, Darmstadt, Germany, we strive every day to improve the futures of people living with cancer. Building on our 350-year global heritage as pharma pioneers, we are focusing our most promising science to target cancer's deepest vulnerabilities, pursuing differentiated molecules to strike cancer at its core. By developing new therapies that can help advance cancer care, we are determined to create a world where more cancer patients will become cancer survivors. Learn more at [www.emdgroup.com](http://www.emdgroup.com).

### **About Precentabart tocentecan (M9140)**

Precentabart tocentecan is an investigational anti-CEACAM5 antibody-drug conjugate (ADC). Leveraging the company's novel linker-payload technology, precentabart tocentecan is the first CEACAM5 ADC with an exatecan payload, a potent topoisomerase inhibitor (TOP1i), which has been rationally designed for stability in circulation and superior cancer cell killing activity. Beyond the direct effect on the target cell, precentabart tocentecan has been shown in preclinical research to induce tumor cell death through a bystander effect in which exatecan permeates the cell membrane to neighboring cells, inducing apoptosis (cell death). This bystander effect within the tumor microenvironment may enhance efficacy. Precentabart tocentecan is currently being evaluated across tumor types with CEACAM5 expression and a high unmet need, including metastatic colorectal cancer (mCRC), gastric cancer (GC), non-small cell lung cancer (NSCLC), and pancreatic ductal adenocarcinoma (PDAC).

### **About Colorectal Cancer**

Colorectal cancer (CRC) is cancer of the colon or rectum, which often arises from benign polyps that eventually turn cancerous. It is the third most common diagnosed malignancy, and the second leading cause of cancer deaths worldwide with approximately 1 in 10 cancer deaths attributed to CRC. Despite new therapies, 5-year survival of stage 4 CRC is <20%. The global burden of CRC has



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substantially increased over time and is expected to increase by 60% to more than 2.2 million new cases and 1.1 million deaths by 2030.<sup>1</sup>

### **About Merck KGaA, Darmstadt, Germany**

Merck KGaA, Darmstadt, Germany, a leading science and technology company, operates across life science, healthcare and electronics. More than 62,000 employees work to make a positive difference to millions of people's lives every day by creating more joyful and sustainable ways to live. From providing products and services that accelerate drug development and manufacturing as well as discovering unique ways to treat the most challenging diseases to enabling the intelligence of devices – the company is everywhere. In 2025, Merck KGaA, Darmstadt, Germany, generated sales of € 21.1 billion in 65 countries.

The company holds the global rights to the name and trademark "Merck" internationally. The only exceptions are the United States and Canada, where the business sectors of Merck KGaA, Darmstadt, Germany, operate as MilliporeSigma in life science, EMD Serono in healthcare and EMD Electronics in electronics. Since its founding in 1668, scientific exploration and responsible entrepreneurship have been key to the company's technological and scientific advances. To this day, the founding family remains the majority owner of the publicly listed company.

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<sup>1</sup> World Health Organization Colorectal cancer: Key facts. Accessed 8 May, 2026. <https://www.who.int/news-room/fact-sheets/detail/colorectal-cancer>

<sup>2</sup> Kopetz S BV, et al. M9140, a novel anti-CEACAM5 antibody–drug conjugate with a potent topoisomerase 1 inhibitor payload (exatecan): preclinical data and results from a phase 1 dose-escalation study in patients with metastatic colorectal cancer (PROCEADE-CRC-01). *Nature Medicine*. 2025

<sup>3</sup> Biller LH, Schrag D. Diagnosis and Treatment of Metastatic Colorectal Cancer: A Review. *JAMA*. 2021;325(7):669-685. doi:10.1001/jama.2021.0106

<sup>4</sup> Xie Y-H, Chen Y-X, Fang J-Y. Comprehensive review of targeted therapy for colorectal cancer. *Signal Transduction and Targeted Therapy*. 2020/03/20 2020;5(1):22. doi:10.1038/s41392-020-0116-z

<sup>5</sup> Martínez-Lago N, Chucla TC, De Castro BA, et al. Efficacy, safety and prognostic factors in patients with refractory metastatic colorectal cancer treated with trifluridine/tipiracil plus bevacizumab in a real-world setting. *Scientific Reports*. 2022/08/26 2022;12(1):14612. doi:10.1038/s41598-022-18871-9