News Release

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May 22, 2025

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EMD Serono Showcases Innovation in Advanced Cancers and Rare Tumors at ASCO 2025

- **Data from Phase 3 MANEUVER study demonstrating significant improvements in physical function and symptoms in patients with tenosynovial giant cell tumor (TGCT) treated with pimicotinib, to be featured in oral presentation**
- **Latest results for potential first-in-class anti-CEACAM5 ADC precemtabart tocentecan (M9140) highlight strong rationale for further development in colorectal cancer (CRC)**

BOSTON, Massachusetts, May 22, 2025 – EMD Serono, the Healthcare business of Merck KGaA, Darmstadt, Germany, in the U.S. and Canada, today announced the presentation of new oncology data across more than 12 tumor types at the 2025 American Society of Clinical Oncology (ASCO) Annual Meeting, May 31 to June 4 in Chicago. The presentations include the Phase 3 MANEUVER data for potentially best-in-class pimicotinib in the treatment of the rare tumor TGCT, as well as data from both company- and investigator-sponsored studies highlighting the company's focus on advancing differentiated molecules to tackle some of the most challenging cancers.

"The new clinical data we are presenting at ASCO showcase our dedication to advancing innovative therapies for a wide range of diseases—spanning from common cancers to rare non-malignant neoplasms," said Victoria Zazulina, M.D., Head of Development Unit, Oncology, for the Healthcare business of Merck KGaA, Darmstadt, Germany. "From encouraging early data for our lead antibody-drug

conjugate, precemtabart tocentecan, in patients with advanced CRC, to new Phase 2 findings and real-world evidence that reinforce the value of BAVENCIO first-line maintenance as a treatment option for advanced bladder cancer, to detailed Phase 3 results for pimicotinib in tenosynovial giant cell tumor, we are working to advance treatments that provide hope to patients and their families."

Highlights of the company's data include:

First presentation of Phase 3 MANEUVER data for pimicotinib in the treatment of TGCT (Abstract 11500)

Detailed results from Part 1 of the Phase 3 MANEUVER study of pimicotinib in the treatment of patients with TGCT, conducted by Abbisko Therapeutics Co., Ltd., will be presented for the first time during the Sarcoma Oral Abstract Session on June 1, at 9:57 a.m. CST. In the trial, pimicotinib significantly improved objective response rate versus placebo, the primary endpoint, as well as all key secondary endpoints, and was well-tolerated. Pimicotinib is being developed by Abbisko Therapeutics; Merck KGaA, Darmstadt, Germany holds the rights to commercialize pimicotinib worldwide.

Latest data for potentially first-in-class precemtabart tocentecan (Abstracts 3038 & TPS3165)

The company continues to progress the clinical investigation of its lead antibody-drug conjugate (ADC), precemtabart tocentecan. New findings from the Phase 1 PROCEADE-CRC 01 study include data from the dose-optimization part in 60 irinotecan-refractory metastatic CRC patients (3L+) demonstrating encouraging efficacy at doses of 2.4mg/kg and 2.8mg/kg every 3 weeks (Q3W) and a predictable and manageable safety profile. These data, which showed a higher ORR and similar safety at the 2.8 mg/kg dose, support the rationale for selecting this as the recommended dose for further development in CRC and other solid tumors, including those cancer types being investigated in the ongoing Phase 1b/2 PROCEADE-PanTumor study (NCT06710132). More mature data for PROCEADE-CRC-01 and details on the design for the PROCEADE-PanTumor study investigating precemtabart tocentecan in patients with locally advanced/metastatic non-small cell lung, gastric, gastroesophageal junction or pancreatic cancer will be presented at the congress.

New findings further building on the benefit from BAVENCIO® (avelumab) in the first-line maintenance setting in advanced bladder cancer (Abstracts 4501, e16561, e23275, 9543)

Interim results from the Phase 2 JAVELIN Bladder Medley trial will be presented, focusing on the efficacy of BAVENCIO in combination with the anti-Trop-2 ADC sacituzumab govitecan (Trodelvy®, Gilead Sciences) for patients with advanced urothelial carcinoma (UC) who are progression-free after first-line platinum-containing chemotherapy. When used in the maintenance setting, the combination therapy significantly improved progression-free survival (PFS) versus BAVENCIO alone (HR 0.49 [95% CI, 0.31-0.76]); median PFS was 11.17 months versus 3.75 months, respectively. Overall survival (OS) data were immature at the time of analysis. Treatment-related adverse events were more frequent in the combination group (97.3%) compared with BAVENCIO monotherapy (63.9%).

The company also will present real-world evidence that reinforces the clinical trial findings from the Phase 3 JAVELIN Bladder 100 study of BAVENCIO as a first-line maintenance therapy in patients with locally advanced/metastatic UC. The data highlight the effectiveness and safety of BAVENCIO in routine clinical practice and heterogenous populations as well as the importance of personalized treatment decision-making.

Select EMD Serono-related abstracts accepted for the ASCO 2025 Annual Meeting include (all times in CDT):

Title	Lead Author	Abstract	Session Information
Pimicotinib			
Pimicotinib in tenosynovial giant cell tumor (TGCT): Efficacy, safety and patient-reported outcomes of Phase 3 MANEUVER study	Niu X	11500	**Session Title:** Sarcoma **Date:** Sunday, June 1, 2025 **Session Time:** 9:45 AM – 12:45 PM **Presentation Time:** 9:45 AM – 9:57 AM **Location:** S100a
Precemtabart tocentecan (M9140)			
Precemtabart tocentecan (M9140), an anti-CEACAM5 ADC with exatecan payload, in patients with metastatic colorectal cancer (mCRC): Results from the dose optimization of the phase 1 PROCEADE CRC-01 study	Kopetz S	3038	**Session Title:** Developmental Therapeutics—Molecularly Targeted Agents and Tumor Biology **Session Title:** Developmental Therapeutics—Molecularly Targeted Agents and Tumor Biology **Date:** Monday, June 2, 2025 **Session Time:** 1:30 PM – 4:30 PM **Location:** Hall A
BAVENCIO® (avelumab)			

Avelumab + sacituzumab govitecan (SG) vs avelumab monotherapy as first-line (1L) maintenance treatment in patients (pts) with advanced urothelial carcinoma (aUC): Interim analysis from the JAVELIN Bladder Medley phase 2 trial	Hoffman-Censit J	4501	**Session Title:** Genitourinary Cancer—Kidney and Bladder **Date:** Sunday, June 1, 2025 **Session Time:** 9:45 AM – 12:45 PM **Presentation Time:** 9:57 AM – 10:09 AM **Location:** Hall D2
Differences in patient (pt) characteristics and therapy choice across treatment (tx) groups in locally advanced or metastatic urothelial cancer (la/mUC) in the US: A survey on unmet patient needs	Milloy N	e16561	**Session Title:** Publication Only: Genitourinary Cancer—Kidney and Bladder
Management and outcomes of rash, peripheral neuropathy (PN), and hyperglycemia (HG) during first-line (1L) treatment (tx) of locally advanced/metastatic urothelial cancer (la/mUC) in a real-world setting	Nizam A	e23275	**Session Title:** Publication Only: Quality Care/Health Services Research
Real-world safety and effectiveness of avelumab in immune-compromised (IC) and non-IC patients with Merkel cell carcinoma (MCC): Results from a prospective German registry (MCC-TRIM)	Becker J	9543	**Session Title:** Melanoma/Skin Cancers

Advancing the Future of Cancer Care

EMD Serono, 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.

About Pimicotinib (ABSK021)

Pimicotinib (ABSK021), which is being developed by Abbisko Therapeutics, is a novel, orally administered, highly selective and potent small-molecule inhibitor of CSF-1R. Pimicotinib has been granted breakthrough therapy designation (BTD) for the treatment of inoperable TGCT by China National Medical Products Administration (NMPA) and the US Food and Drug Administration (FDA), and priority medicine (PRIME) designation from the European Medicines Agency (EMA). Merck KGaA, Darmstadt, Germany, holds worldwide commercialization rights for pimicotinib.

About precemtabart tocentecan (M9140)

Precemtabart tocentecan (previously known as M9140) is an investigational anti-CEACAM5 antibody-drug conjugate (ADC). Leveraging the company's novel linker-payload technology, precemtabart 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, precemtabart tocentecan has been shown in preclinical research to induce tumor cell death through a bystander effect permeating the cell membrane to neighboring cells, inducing apoptosis (cell death). This bystander effect within the tumor microenvironment may enhance efficacy, particularly in tumors with heterogenous CEACAM5 expression. Precemtabart 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 BAVENCIO® (avelumab)

BAVENCIO is a human anti-programmed death ligand-1 (PD-L1) antibody. BAVENCIO has been shown in preclinical models to engage both the adaptive and innate immune functions. By blocking the interaction of PD-L1 with PD-1 receptors, BAVENCIO has been shown to release the suppression of the T cell-mediated antitumor immune response in preclinical models.

BAVENCIO Approved Indications

BAVENCIO® (avelumab) is indicated in the US for the maintenance treatment of patients with locally advanced or metastatic urothelial carcinoma (UC) that has not progressed with first-line platinum-containing chemotherapy. BAVENCIO is also indicated for the treatment of patients with locally advanced or metastatic UC who have disease progression during or following platinum-containing chemotherapy, or have disease progression within 12 months of neoadjuvant or adjuvant treatment with platinum-containing chemotherapy.

BAVENCIO in combination with axitinib is indicated in the US for the first-line treatment of patients with advanced renal cell carcinoma (RCC).

In the US, BAVENCIO is indicated for the treatment of adults and pediatric patients 12 years and older with metastatic Merkel cell carcinoma (MCC).

BAVENCIO is currently approved for at least one indication for patients in more than 50 countries.

BAVENCIO Important Safety Information from the US FDA-Approved Label
BAVENCIO can cause **severe and fatal immune-mediated adverse reactions** in any organ system or tissue and at any time after starting treatment with a PD-1/PD-L1 blocking antibody, including after discontinuation of treatment.

Early identification and management of immune-mediated adverse reactions are essential to ensure safe use of PD-1/PD-L1 blocking antibodies. Monitor patients closely for symptoms and signs that may be clinical manifestations of underlying immune-mediated adverse reactions. Evaluate liver enzymes, creatinine, and thyroid function at baseline and periodically during treatment. In cases of suspected immune-mediated adverse reactions, initiate appropriate workup to exclude alternative etiologies, including infection. Institute medical management promptly, including specialty consultation as appropriate.

No dose reduction for BAVENCIO is recommended. For immune-mediated adverse reactions, withhold or permanently discontinue BAVENCIO depending on severity. In general, withhold BAVENCIO for severe (Grade 3) immune-mediated adverse reactions. Permanently discontinue BAVENCIO for life-threatening (Grade 4) immune-mediated adverse reactions, recurrent severe (Grade 3) immune-mediated reactions that require systemic immunosuppressive treatment, or an inability to reduce corticosteroid dose to 10 mg or less of prednisone or equivalent per day within 12 weeks of initiating corticosteroids. In general, if BAVENCIO requires interruption or discontinuation, administer systemic corticosteroid therapy (1 to 2 mg/kg/day prednisone or equivalent) until improvement to Grade 1 or less. Upon improvement to Grade 1 or less, initiate corticosteroid taper and continue to taper over at least 1 month. Consider administration of other systemic immunosuppressants in patients whose immune-mediated adverse reactions are not controlled with corticosteroid therapy. Toxicity management guidelines for adverse reactions that do not necessarily require

systemic corticosteroids (eg, endocrinopathies and dermatologic reactions) are discussed in subsequent sections.

BAVENCIO can cause **immune-mediated pneumonitis**. Withhold BAVENCIO for Grade 2, and permanently discontinue for Grade 3 or Grade 4 pneumonitis. Immune-mediated pneumonitis occurred in 1.1% (21/1854) of patients, including fatal (0.1%), Grade 4 (0.1%), Grade 3 (0.3%), and Grade 2 (0.6%) adverse reactions. Systemic corticosteroids were required in all (21/21) patients with pneumonitis.

BAVENCIO can cause **immune-mediated colitis**. The primary component of immune-mediated colitis consisted of diarrhea. Cytomegalovirus infection/reactivation has been reported in patients with corticosteroid-refractory immune-mediated colitis. In cases of corticosteroid-refractory colitis, consider repeating infectious workup to exclude alternative etiologies. Withhold BAVENCIO for Grade 2 or Grade 3, and permanently discontinue for Grade 4 colitis. Immune-mediated colitis occurred in 1.5% (27/1854) of patients, including Grade 3 (0.4%) and Grade 2 (0.8%) adverse reactions. Systemic corticosteroids were required in all (27/27) patients with colitis.

BAVENCIO can cause **hepatotoxicity and immune-mediated hepatitis**. Withhold or permanently discontinue BAVENCIO based on tumor involvement of the liver and severity of aspartate aminotransferase (AST), alanine aminotransferase (ALT), or total bilirubin elevation. Immune-mediated hepatitis occurred with BAVENCIO as a single agent in 1.1% (20/1854) of patients, including fatal (0.1%), Grade 3 (0.8%), and Grade 2 (0.2%) adverse reactions. Systemic corticosteroids were required in all (20/20) patients with hepatitis.

BAVENCIO can cause primary or secondary **immune-mediated adrenal insufficiency**. For Grade 2 or higher adrenal insufficiency, initiate symptomatic treatment, including hormone replacement, as clinically indicated. Withhold BAVENCIO for Grade 3 or Grade 4 endocrinopathies until clinically stable or permanently discontinue depending on severity. Immune-mediated adrenal insufficiency occurred in 0.6% (11/1854) of patients, including Grade 3 (0.1%) and

Grade 2 (0.4%) adverse reactions. Systemic corticosteroids were required in all (11/11) patients with adrenal insufficiency.

BAVENCIO can cause **immune-mediated hypophysitis**. Hypophysitis can present with acute symptoms associated with mass effect such as headache, photophobia, or visual field defects. Hypophysitis can cause hypopituitarism. Initiate hormone replacement, as clinically indicated. Withhold BAVENCIO for Grade 3 or Grade 4 endocrinopathies until clinically stable or permanently discontinue depending on severity. Immune-mediated pituitary disorders occurred in 0.1% (1/1854) of patients, which was a Grade 2 (0.1%) adverse reaction.

BAVENCIO can cause **immune-mediated thyroid disorders**. Thyroiditis can present with or without endocrinopathy. Hypothyroidism can follow hyperthyroidism. Initiate hormone replacement for hypothyroidism or institute medical management of hyperthyroidism, as clinically indicated. Withhold BAVENCIO for Grade 3 or Grade 4 endocrinopathies until clinically stable or permanently discontinue depending on severity. Thyroiditis occurred in 0.2% (4/1854) of patients, including Grade 2 (0.1%) adverse reactions. Hyperthyroidism occurred in 0.4% (8/1854) of patients, including Grade 2 (0.3%) adverse reactions. Systemic corticosteroids were required in 25% (2/8) of patients with hyperthyroidism. Hypothyroidism occurred in 5% (97/1854) of patients, including Grade 3 (0.2%) and Grade 2 (3.6%) adverse reactions. Systemic corticosteroids were required in 6% (6/97) of patients with hypothyroidism.

BAVENCIO can cause **immune-mediated type I diabetes mellitus**, which can present with diabetic ketoacidosis. Monitor patients for hyperglycemia or other signs and symptoms of diabetes. Initiate treatment with insulin as clinically indicated. Withhold BAVENCIO for Grade 3 or Grade 4 endocrinopathies until clinically stable or permanently discontinue depending on severity. Immune-mediated type I diabetes mellitus occurred in 0.2% (3/1854) of patients, including Grade 3 (0.2%) adverse reactions.

BAVENCIO can cause **immune-mediated nephritis with renal dysfunction**. Withhold BAVENCIO for Grade 2 or Grade 3, and permanently discontinue for Grade 4 increased blood creatinine. Immune-mediated nephritis with renal dysfunction

occurred in 0.1% (2/1854) of patients, including Grade 3 (0.1%) and Grade 2 (0.1%) adverse reactions. Systemic corticosteroids were required in all (2/2) patients with nephritis with renal dysfunction.

BAVENCIO can cause **immune-mediated dermatologic adverse reactions**, including rash or dermatitis. Exfoliative dermatitis including Stevens Johnson Syndrome (SJS), drug rash with eosinophilia and systemic symptoms (DRESS), and toxic epidermal necrolysis (TEN), has occurred with PD-1/PD-L1 blocking antibodies. Topical emollients and/or topical corticosteroids may be adequate to treat mild to moderate non-exfoliative rashes. Withhold BAVENCIO for suspected and permanently discontinue for confirmed SJS, TEN, or DRESS. Immune-mediated dermatologic adverse reactions occurred in 6% (108/1854) of patients, including Grade 3 (0.1%) and Grade 2 (1.9%) adverse reactions. Systemic corticosteroids were required in 25% (27/108) of patients with dermatologic adverse reactions.

BAVENCIO can result in **other immune-mediated adverse reactions**. Other clinically significant immune-mediated adverse reactions occurred at an incidence of <1% in patients who received BAVENCIO or were reported with the use of other PD-1/PD-L1 blocking antibodies. For **myocarditis**, permanently discontinue BAVENCIO for Grade 2, Grade 3, or Grade 4. For **neurological toxicities**, withhold BAVENCIO for Grade 2 and permanently discontinue for Grade 3 or Grade 4.

BAVENCIO can cause severe or life-threatening **infusion-related reactions**. Premedicate patients with an antihistamine and acetaminophen prior to the first 4 infusions and for subsequent infusions based upon clinical judgment and presence/severity of prior infusion reactions. Monitor patients for signs and symptoms of infusion-related reactions, including pyrexia, chills, flushing, hypotension, dyspnea, wheezing, back pain, abdominal pain, and urticaria. Interrupt or slow the rate of infusion for Grade 1 or Grade 2 infusion-related reactions. Permanently discontinue BAVENCIO for Grade 3 or Grade 4 infusion-related reactions. Infusion-related reactions occurred in 26% of patients, including three (0.2%) Grade 4 and ten (0.5%) Grade 3 infusion-related reactions. Eleven (85%) of the 13 patients with Grade ≥3 reactions were treated with intravenous corticosteroids.

Fatal and other serious **complications of allogeneic hematopoietic stem cell transplantation (HSCT)** can occur in patients who receive HSCT before or after being treated with a PD-1/PD-L1 blocking antibody. Follow patients closely for evidence of transplant-related complications and intervene promptly. Consider the benefit versus risks of treatment with a PD-1/PD-L1 blocking antibody prior to or after an allogeneic HSCT.

BAVENCIO can cause **fetal harm** when administered to a pregnant woman. Advise patients of the potential risk to a fetus including the risk of fetal death. Advise females of childbearing potential to use effective contraception during treatment with BAVENCIO and for at least 1 month after the last dose of BAVENCIO. It is not known whether BAVENCIO is excreted in human milk. Advise a lactating woman **not to breastfeed** during treatment and for at least 1 month after the last dose of BAVENCIO due to the potential for serious adverse reactions in breastfed infants.

The most common adverse reactions (all grades, ≥20%) in patients with **metastatic Merkel cell carcinoma (MCC)** were fatigue (47%), musculoskeletal pain (29%), infusion-related reaction (26%), rash (25%), nausea (23%), constipation (22%), cough (22%), and diarrhea (21%).

Laboratory abnormalities worsening from baseline (all grades, ≥20%) in patients with **metastatic MCC** were decreased lymphocyte count (51%), decreased hemoglobin (40%), increased aspartate aminotransferase (31%), decreased platelet count (23%), increased alanine aminotransferase (22%), and increased lipase (21%).

A **fatal adverse reaction** (sepsis) occurred in one (0.3%) patient with **locally advanced or metastatic urothelial carcinoma (UC)** receiving BAVENCIO + best supportive care (BSC) as first-line maintenance treatment. In patients with previously treated locally advanced or metastatic UC, fourteen patients (6%) who were treated with BAVENCIO experienced either pneumonitis, respiratory failure, sepsis/urosepsis, cerebrovascular accident, or gastrointestinal adverse events, which led to death.

The most common adverse reactions (all grades, ≥20%) in patients with **locally advanced or metastatic UC** receiving BAVENCIO + BSC (vs BSC alone) as first-line maintenance treatment were fatigue (35% vs 13%), musculoskeletal pain (24% vs 15%), urinary tract infection (20% vs 11%), and rash (20% vs 2.3%). In patients with previously treated locally advanced or metastatic UC receiving BAVENCIO, the most common adverse reactions (all grades, ≥20%) were fatigue, infusion-related reaction, musculoskeletal pain, nausea, decreased appetite, and urinary tract infection.

Selected laboratory abnormalities worsening from baseline (all grades, ≥20%) in patients with **locally advanced or metastatic UC** receiving BAVENCIO + BSC (vs BSC alone) as first-line maintenance treatment were blood triglycerides increased (34% vs 28%), alkaline phosphatase increased (30% vs 20%), blood sodium decreased (28% vs 20%), lipase increased (25% vs 16%), aspartate aminotransferase (AST) increased (24% vs 12%), blood potassium increased (24% vs 16%), alanine aminotransferase (ALT) increased (24% vs 12%), blood cholesterol increased (22% vs 16%), serum amylase increased (21% vs 12%), hemoglobin decreased (28% vs 18%), and white blood cell decreased (20% vs 10%).

Please see full Prescribing Information and Medication Guide.

About EMD Serono, Inc.
EMD Serono - the healthcare business of Merck KGaA, Darmstadt, Germany in the U.S. and Canada - aspires to create, improve and prolong life for people living with difficult-to-treat conditions like infertility, multiple sclerosis and cancer. The business is imagining the future of healthcare by working to translate the discovery of molecules into potentially meaningful outcomes for people with serious unmet medical needs. EMD Serono's global roots go back more than 350 years with Merck KGaA, Darmstadt, Germany. Today, the business has approximately 1,050 employees around the country with commercial, clinical and research operations in Massachusetts. www.emdserono.com.

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 2024, Merck KGaA, Darmstadt, Germany, generated sales of € 21.2 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.

News Release

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