

News Release

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Merck KGaA, Darmstadt, Germany Presents Data on Bifunctional Immunotherapy M7824 at ASCO 2018 Gastrointestinal Cancers Symposium

- **Company to present three abstracts on M7824, its investigational early phase PD-L1/TGF- β bifunctional immuno-oncology asset**
- **Noteworthy data includes encouraging preliminary expansion cohort data in gastric cancer**

Darmstadt, Germany, January 16, 2018 – Merck KGaA, Darmstadt, Germany, a leading science and technology company which operates its healthcare business in the U.S. and Canada as EMD Serono, today announced three abstracts on M7824, an investigational early phase PD-L1/TGF- β bifunctional immuno-oncology asset, will be presented at the American Society of Clinical Oncology 2018 Gastrointestinal Cancers Symposium, January 19–21, 2018, in San Francisco, California. These data provide preliminary evidence that combining the anti-PD-L1 mechanism and TGF- β trap in one molecule may generate anti-tumor activity in some heavily pretreated patient populations who are in significant need of therapies that can extend survival.

“The data at ASCO GI includes some of the first tumor-specific preliminary cohort data for M7824, with encouraging results in gastric cancer,” said Luciano Rossetti, M.D., Executive Vice President, Global Head of Research & Development at the Biopharma business of Merck KGaA, Darmstadt, Germany. “The data adds to our deepening knowledge of the therapeutic potential of this bi-functional immunotherapy, allowing us to further sharpen our focus on indications where we have the highest potential to make a real difference for patients.”

In 31 heavily pretreated Asian patients with recurrent or refractory unresectable advanced gastric and gastroesophageal adenocarcinoma and unselected for PD-L1

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status, preliminary data show initial clinical activity based on investigator-assessed best overall response (BOR), with an unconfirmed overall response rate (ORR) of 25.8%, confirmed ORR of 19.4% and a disease control rate of 35.5% observed. The safety profile was in line with that anticipated in such a heavily pretreated population. More information for all of the data presented at ASCO GI is included below.

Merck KGaA, Darmstadt, Germany, is committed to exploring an array of targets and taking creative scientific approaches to developing novel therapies for hard-to-treat cancers. With the belief that rational combination is the key to the future of new and more efficacious treatment options, Merck KGaA, Darmstadt, Germany, has a particular focus on combination therapies, whether it be with chemotherapy/radiotherapy, other targeted therapies and/or immunotherapies from its own or external portfolios. The strength of Merck KGaA, Darmstadt, Germany's promising oncology development program and growing presence in the field of immuno-oncology demonstrates how the company is re-imagining the way cancer care is delivered.

M7824 ASCO GI Abstracts

Abstract 100 – *M7824 (MSB0011359C), a bifunctional fusion protein targeting PD-L1 and TGF- β , in Asian patients with pretreated recurrent or refractory gastric cancer: preliminary results from a phase 1 trial*

- In 31 heavily pretreated Asian patients with recurrent or refractory unresectable advanced gastric and gastroesophageal adenocarcinoma and unselected for PD-L1 status, preliminary data show initial clinical activity based on investigator-assessed best overall response (BOR), with an unconfirmed ORR of 25.8%, confirmed ORR of 19.4% and a disease control rate of 35.5% observed: For confirmed responses, 1 patient had a confirmed complete response (ongoing at 5.4+ months), 5 had a confirmed partial response (4 still ongoing at 1.5+, 3.6+, 5.4+ and 6.9+ months) and 6 patients had stable disease
- The safety profile was in line with that anticipated in such a heavily pretreated population. A total of 15 patients (48.4%) experienced treatment-related adverse events (TRAEs), most commonly maculopapular rash (22.6%). Seven patients reported \geq grade 3 TRAEs, including rash, anemia and diarrhea. One

patient died following an AE considered possibly treatment-related (reported as “sudden death”) – the investigator cited suspected rupture of preexisting thoracic aortic aneurysm as other probable cause

- Biomarker analysis to identify patient subpopulations are ongoing and will be reported at a later time point

Abstract 762 – M7824 (MSB0011359C), a bifunctional fusion protein targeting PD-L1 and TGF- β , in patients with heavily pretreated CRC: preliminary results from a phase I trial

- In 32 heavily pretreated patients with recurrent or refractory unresectable advanced colorectal cancer (CRC), preliminary data showed a confirmed PR (ongoing at 8.3 months) in one patient, who had CRC that was microsatellite stable (MSS), consensus molecular subtype (CMS) 4, KRAS mutant (mt) and PD-L1+
- The safety profile was in line with that anticipated in such a heavily pretreated patient population. Four patients (12.5%) experienced grade 3 TRAEs: adrenal insufficiency, anemia, blood bilirubin increased, enteritis (leading to discontinuation) and fatigue. There were no grade ≥ 4 TRAEs or treatment-related deaths

Abstract 764 – M7824 (MSB0011359C), a bifunctional fusion protein targeting PD-L1 and TGF- β , in Asian patients with advanced solid tumors

- Fourteen heavily pretreated patients received M7824 at 3, 10 or 20 mg/kg q2w until confirmed progressive disease, unacceptable toxicity or trial withdrawal. The median duration of treatment was 5.9 weeks
- Signs of clinical activity were seen across all dose levels, and maximum tolerated dose was not reached. Two patients had a confirmed partial response (CRC [associated with Lynch syndrome] and ovarian cancer) and 3 patients had confirmed stable disease (gastric, gastroesophageal junction and adenoid cystic cancer)
- A total of 3 patients (21.4%) reported \geq grade 3 TRAEs, including hyponatremia, increased blood creatine phosphokinase and hypopituitarism. Two of these patients discontinued treatment following grade 3 TRAEs (intracranial tumor hemorrhage and reversible hypoacusis)

About M7824

M7824 is an investigational bifunctional immunotherapy that is designed to bring together the anti-PD-L1 mechanism and 'fuse' it with a transforming growth factor β (TGF- β) trap. M7824 is designed to simultaneously block the two immuno-inhibitory pathways – targeting both pathways aims to control tumor growth by potentially restoring and enhancing anti-tumor responses. By combining two targeting mechanisms against cancer cells in one molecule, it also aims to increase safety and efficacy, compared to monotherapy approaches.

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About Merck KGaA, Darmstadt, Germany

Merck KGaA, Darmstadt, Germany, is a leading science and technology company in healthcare, life science and performance materials. Around 50,000 employees work to further develop technologies that improve and enhance life – from biopharmaceutical therapies to treat cancer or multiple sclerosis, cutting-edge systems for scientific research and production, to liquid crystals for smartphones and LCD televisions. In 2016, Merck KGaA, Darmstadt, Germany, generated sales of € 15.0 billion in 66 countries. Founded in 1668, Merck KGaA, Darmstadt, Germany, is the world's oldest pharmaceutical and chemical company. The founding family remains the majority owner of the publicly listed corporate group. Merck KGaA, Darmstadt, Germany, holds the global rights to the "Merck" name and brand. The only exceptions are the United States and Canada, where the company operates as EMD Serono, MilliporeSigma and EMD Performance Materials.