



Your Contact

Gangolf Schrimpf +49 6151 72-9591
Investor Relations +49 6151 72-3321

News Release

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Merck KGaA, Darmstadt, Germany, Presents Details on Immuno-Oncology Program Including First-in-Man Milestone with Investigational Bi-Functional Immunotherapy

- **Early pipeline projects include investigational bi-functional immunotherapy expected to control tumor growth**
- **Alliance with Pfizer on track with more than 1,000 patients treated with avelumab to date collaboration with Pfizer on up to 20 clinical programs**
- **First potential commercial launch of avelumab expected in 2017; working toward at least one additional potential launch per year through 2022**

Darmstadt, Germany, October 1, 2015 – Merck KGaA, Darmstadt, Germany, a leading company for innovative and top-quality high-tech products in healthcare, life science and performance materials, today announced gave an update on key immuno-oncology and oncology research and development projects, illustrating visible progress across all pipeline stages.

Among others, the company announced that it started investigating a novel, potential first-in-class bi-functional immunotherapy in clinical trials with the potential to offer an alternative therapy to anti-PD-1/anti-PD-L1 and other immunotherapies. Merck KGaA, Darmstadt, Germany, also showed good progress in its avelumab development program, which it is driving together with Pfizer. If successful, the companies expect the first potential commercial launch for avelumab in 2017, and are working toward at least one additional potential launch per year through 2022.



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“We have a focused and differentiated pipeline in immuno-oncology, oncology and immunology that has the potential to make a substantial difference in the lives of patients,” said Luciano Rossetti, Head of Global R&D at the biopharmaceutical business of Merck KGaA, Darmstadt, Germany, in an investor call following presentations at this year’s European Cancer Congress (ECC) in Vienna, which took place Sept. 25 - 29. “Our priorities include accelerating high-priority programs and ensuring launch success to secure long-term growth.”

Merck KGaA, Darmstadt, Germany, has been rebuilding its research and development organization over the past four years, with new leadership and improved R&D operating model. Rigorous project prioritization, increased efficiency and more agile decision making has allowed the company to progress its R&D productivity. Merck KGaA, Darmstadt, Germany, is on track to deliver a continuous flow of innovative specialty medicines in areas of high unmet medical need, including several promising earlier stage assets.

More than 3,000 patients expected to be treated with Avelumab by 2016

Regarding the avelumab clinical development program, Merck KGaA, Darmstadt, Germany, said it is on track to meet its 2015 goals of collaborating on up to 20 clinical programs, including initiating up to six pivotal trials. By the end of 2016, Merck KGaA, Darmstadt, Germany, expects more than 3,000 patients to be treated across more than 15 tumor types and lines of therapy.

In September, the US Food and Drug Administration (FDA) granted Orphan Drug Designation (ODD) for avelumab in Merkel cell carcinoma (MCC). MCC is a very rare disease in which malignant (cancer) cells form in the skin. This orphan drug designation does not guarantee market approval, but could imply seven years of market exclusivity upon approval and other incentives.

Beyond avelumab, Merck KGaA, Darmstadt, Germany, today also disclosed details on other key immuno-oncology programs aimed at helping patients fight difficult-to-treat



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cancers. These projects include its CAR-T/Intrexon T-cell therapies, which could form the next cornerstone of cancer immunotherapy. The innovative chimeric antigen receptor T-cell treatments modulate the immune system's natural ability to fight tumors.

In addition, Merck KGaA, Darmstadt, Germany, gave details on its investigational molecule, M7824, for which it has initiated and treated the first patient in a phase I, open-label, multiple-ascending clinical trial, targeting to enroll 106 patients. This potential first-in-class bi-functional immunotherapy is designed to simultaneously block two immunoinhibitory pathways that are commonly used by cancer cells to evade the immune system, thereby controlling tumor growth by restoring and enhancing anti-tumor immune responses.

“The initiation of the M7824 clinical trial marks the next milestone in our strategy to build an innovative portfolio of cancer immunotherapies that may work synergistically to potentially maximize patient benefit,” Rossetti said. “This is the first phase I trial industry-wide for this class of molecule and we expect to see key data during the second half of 2016.”

In the broader field of oncology, Merck KGaA, Darmstadt, Germany, reiterated that it expects to have key data on its oncology treatment evofosfamide, a hypoxia-activated pro drug currently tested in clinical phase III trials in soft tissue sarcoma and pancreatic cancer, during the fourth quarter of 2015. In addition, the company disclosed details of its tepotinib program, an investigational small molecule inhibitor of the c-met receptor tyrosine kinase, as well as its DNA-PK inhibitor M3814, which has the potential for a first-in-class orally administered selective DNA-PK inhibitor.

The webcast can be followed live [here](#) (starting at 14:00 CEST), the presentation will be available at the Investor Relations [section](#) of our website.



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Merck KGaA of Darmstadt, Germany, is a leading company for innovative and top-quality high-tech products in healthcare, life science and performance materials. The company has six businesses – Biopharmaceuticals, Consumer Health, Allergopharma, Biosimilars, Life Science and Performance Materials – and generated sales of € 11.3 billion in 2014. Around 39,000 employees work in 66 countries to improve the quality of life for patients, to foster the success of customers and to help meet global challenges. Merck KGaA, Darmstadt, Germany, is the world's oldest pharmaceutical and chemical company – since 1668, the company has stood for innovation, business success and responsible entrepreneurship. Holding an approximately 70% interest, the founding family remains the majority owner of the company to this day. Merck KGaA, Darmstadt, Germany holds the global rights to the Merck name and brand. The only exceptions are Canada and the United States, where the company operates as EMD Serono, EMD Millipore and EMD Performance Materials.