

News Release

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Corporate Ventures Fund of Merck KGaA, Darmstadt, Germany, Creates New Immuno-Oncology Company iOnctura

- **iOnctura is set up to develop a pipeline of assets targeting immunosuppression in the tumour microenvironment**
- **The company will progress its portfolio of assets seamlessly into clinical evaluation, in collaboration with one of its shareholders Cancer Research Technology (CRT)**
- **The vision of iOnctura is - through combination with its pipeline - to significantly improve the clinical efficacy and expand the utility of checkpoint inhibitors**

Darmstadt, Germany, June 20, 2016 – Merck KGaA, Darmstadt, Germany, a leading science and technology company, today announced its corporate venture arm created iOnctura SA, Geneva, Switzerland. This immuno-oncology spin-out company was formed around two assets from the Healthcare R&D portfolio of Merck KGaA, Darmstadt, Germany, and three assets from Cancer Research Technology (CRT). CRT is the commercial arm of Cancer Research UK, London, UK. The Corporate Ventures Fund of Merck KGaA, Darmstadt, Germany, will manage the investment and will be represented on iOnctura's board of directors.

"Our goal is to modulate key culprits of immunosuppression in the tumor microenvironment to maximize the therapeutic potential of checkpoint inhibitors for patients," said Catherine Pickering, CEO and co-founder of iOnctura. "Through our key alliances with CRT and Merck KGaA, Darmstadt, Germany, we are optimally positioned to explore novel combination therapies and advance them quickly to cancer patients."

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iOnctura aims to develop a pipeline of selected assets that target and modulate mechanisms that drive immunosuppression in the tumor microenvironment (TME). Such immunosuppression has been shown to be one of the main causes behind a significant number of patients not responding to first generation checkpoint inhibitors. iOnctura, through its alliances with Merck KGaA, Darmstadt, Germany, and CRT, has already built a pipeline of promising programs and entered a research collaboration with CRT Discovery Laboratories. In exchange for the exclusive global option to license three immuno-oncology assets from CRT, iOnctura will provide CRT with an initial equity holding in the company and will make further payments for the achievement of late development and approval milestones as well as royalties on net sales. iOnctura has also secured access to future supply of avelumab, being co-developed and co-commercialized by Merck KGaA, Darmstadt, Germany, and Pfizer, which will enable acceleration into initial clinical proof of concept studies.

Stuart Farrow, CRT's director of biology, said: "We're delighted that these three potential new cancer treatments, partly developed by our drug discovery laboratories alongside leading Cancer Research UK-funded scientists, have been prioritized for further development through the formation of this new company. The ongoing support by our drug discovery laboratories will hopefully help build a strong development pipeline for iOnctura."

The Corporate Ventures Fund of Merck KGaA, Darmstadt, Germany, is providing the initial seed funding to iOnctura. Hakan Goker, Senior Investment Director at the Corporate Ventures Fund of Merck KGaA, Darmstadt, Germany, and Keno Guttierrez, Investment Director, will represent the Corporate Ventures Fund on iOnctura's board of directors.

About iOnctura

[iOnctura](#) is a biopharmaceutical company focusing on novel therapeutics to modulate key culprits of immunosuppression in the tumor microenvironment. Immune checkpoint inhibitors (eg PD/PD-L1) have shown remarkable effectiveness for some but not for all cancer patients. iOnctura aims to improve current immune checkpoint therapies by developing novel drugs with potential best-in-class safety and efficacy profiles that when combined with checkpoint inhibition have the potential to optimize clinical outcomes. Through its partnerships with Merck KGaA, Darmstadt, Germany, and Cancer Research Technology (the commercial arm of Cancer Research UK, London, UK), iOnctura has established a pipeline of preclinical molecules to advance towards the clinic in combination with immuno-oncology assets from Merck KGaA, Darmstadt, Germany. iOnctura is supported by a world renowned scientific advisory board and, with its access to CRT's drug discovery labs and network of academic collaborators, is well-positioned to rapidly establish novel combination therapies in the field of cancer immunology. Headquartered in Geneva, Switzerland, iOnctura was founded by the Corporate Ventures Fund of Merck KGaA, Darmstadt, Germany, in June 2017.

Corporate Ventures Fund of Merck KGaA, Darmstadt, Germany

The new [fund](#) is the strategic, corporate venture capital arm of Merck KGaA, Darmstadt, Germany. Its mandate is to invest in innovative technologies and products with the potential to significantly impact the core business areas of Merck KGaA, Darmstadt, Germany. From our headquarters in Amsterdam and offices in the US and Israel we invest globally in transformational ideas driven by great entrepreneurs. The Corporate Ventures fund takes an active role in its portfolio companies and teams up with entrepreneurs and co-investors to translate innovation towards commercial success. The fund has a significant focus on early-stage investing and company creation including the creation of spin-offs to leverage the science and technology base of Merck KGaA, Darmstadt, Germany.

About Cancer Research Technology

[Cancer Research Technology Limited](#) (CRT) is a specialist commercialization and development company, which aims to develop new discoveries in cancer research for the benefit of cancer patients. CRT works closely with leading international cancer scientists and their institutes to protect intellectual property arising from their research and to establish links with commercial partners. CRT facilitates the discovery, development and marketing of new cancer therapeutics, vaccines, diagnostics and enabling technologies. CRT is wholly owned by Cancer Research UK, the world's leading cancer charity dedicated to saving lives through research.

About Avelumab

Avelumab is a human antibody specific for a protein called PD-L1, or programmed death ligand-1. Avelumab is designed to potentially engage both the adaptive and innate immune systems. By binding to PD-L1, avelumab is thought to prevent tumor cells from using PD-L1 for protection against white blood cells, such as T-cells, exposing them to anti-tumor responses. Avelumab has been shown to induce antibody-dependent cell-mediated cytotoxicity (ADCC) in vitro. In November 2014, Merck KGaA, Darmstadt, Germany, and Pfizer announced a strategic alliance to co-develop and co-commercialize avelumab.

Avelumab is currently being evaluated in the JAVELIN clinical development program, which involves at least 30 clinical programs, including nine Phase III trials, and more than 5,200 patients evaluated across more than 15 different tumor types, including gastric/gastroesophageal junction, non-small cell lung cancer, renal cell carcinoma and ovarian cancer. For a comprehensive list of all avelumab trials, please visit clinicaltrials.gov

Indications

The US Food and Drug Administration (FDA) granted accelerated approval for avelumab (BAVENCIO®) for the treatment of (i) metastatic Merkel cell carcinoma (mMCC) in adults and pediatric patients 12 years and older and (ii) patients with locally advanced or metastatic urothelial carcinoma (UC) who have disease progression during or following platinum-containing chemotherapy, or who have disease progression within 12 months of neoadjuvant or adjuvant treatment with platinum-containing chemotherapy. These indications are approved under accelerated approval based on tumor response rate and duration of response. Continued approval for these indications may be contingent upon verification and description of clinical benefit in confirmatory trials. Avelumab is not approved for any indication in any market outside the US.

Important Safety Information

The warnings and precautions for avelumab (BAVENCIO®) include immune-mediated adverse reactions (such as pneumonitis, hepatitis, colitis, endocrinopathies, nephritis and renal dysfunction and other adverse reactions), infusion-related reactions and embryo-fetal toxicity.

Common adverse reactions (reported in at least 20% of patients) in patients treated with avelumab include fatigue, musculoskeletal pain, diarrhea, nausea, infusion-related reaction, peripheral edema, decreased appetite/hypophagia, urinary tract infection and rash.

Alliance between Merck KGaA, Darmstadt, Germany, and Pfizer Inc., New York, US

Immuno-oncology is a top priority for Merck KGaA, Darmstadt, Germany, and Pfizer Inc. The global strategic alliance between Merck KGaA, Darmstadt, Germany, and Pfizer Inc., New York, US, enables the companies to benefit from each other's strengths and capabilities and further explore the therapeutic potential of avelumab, an anti-PD-L1 antibody initially discovered and developed by Merck KGaA,

Darmstadt, Germany. The immuno-oncology alliance will jointly develop and commercialize avelumab and advance Pfizer's PD-1 antibody. The alliance is focused on developing high-priority international clinical programs to investigate avelumab as a monotherapy, as well as in combination regimens, and is striving to find new ways to treat cancer.

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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.