

Dealdoc

Co-development and co-marketing agreement for MSB0010718C

Merck KGaA Pfizer

Nov 17 2014

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Merck KGaA Companies: Pfizer

Announcement date: Nov 17 2014

Deal value, US\$m: 2850 : sum of upfront and milestone payments Related contracts: Co-promotion agreement for Xalcori

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Details

Announcement date: Nov 17 2014 Bigpharma Industry sectors: Pharmaceutical Compound name: MSB0010718C **Exclusivity:** Exclusive Asset type: Compound Therapy areas: Oncology Antibodies Technology types: Small molecules Co-development Co-promotion Deal components: Collaborative R&D

> Licensing Phase II

Stages of development: Geographic focus: Worldwide

Financials

Deal value, US\$m: 2850 : sum of upfront and milestone payments

Upfront, US\$m: 850 : upfront payment

Milestones, US\$m: 2000 : regulatory and commercial milestone payments

n/d: revenues obtained from selling any anti-PD-L1 or anti-PD-1 Royalty rates, %: products generated from this collaboration will be shared

Semi-quant royalties: Revenue share

Funding, US\$m: n/d: jointly fund all development and commercialization costs

Termsheet

Merck KGaA has entered into a global agreement with Pfizer to co-develop and co-commercialize MSB0010718C, an investigational anti-PD-L1 antibody currently in development by Merck KGaA as a potential treatment for multiple tumor types to accelerate the two companies' presence in immuno-oncology.

The asset will be developed as a single agent as well as in various combinations with Pfizer's and Merck KGaA's broad portfolio of approved and investigational pipeline candidates.

The two companies will also combine resources and expertise to advance Pfizer's anti-PD-1 antibody into Phase 1 trials.

As part of the agreement, Merck KGaA will co-promote Pfizer's XALKORI, a medicine to treat non-small cell lung cancer, in the United States and several other key markets.

Merck KGaA will receive an upfront payment of \$850 million (around € 680 million) and is eligible to receive regulatory and commercial milestone payments up to \$ 2.0 billion.

Both companies will jointly fund all development and commercialization costs and all revenues obtained from selling any anti-PD-L1 or anti-PD-1 products generated from this collaboration will be shared.

Press Release

Merck KGaA, Darmstadt, Germany, Announces Global Strategic Alliance with Pfizer on Anti-PD-L1 to Accelerate Presence in Immuno-Oncology

Merck KGaA, Darmstadt, Germany, and Pfizer will jointly develop and commercialize Merck KGaA, Darmstadt, Germany,'s anti-PD-L1

Joint investment and combined strengths and capabilities will further maximize potential of Merck KGaA, Darmstadt, Germany,'s asset in the highly competitive anti-PD-1 / anti-PD-L1 space

Up to 20 high priority immuno-oncology clinical development programs expected to commence in 2015, including pivotal registration studies

Alliance accelerates Merck KGaA, Darmstadt, Germany,'s entry into the US oncology market November 17, 2014 03:40 AM Eastern Standard Time DARMSTADT, Germany--(BUSINESS WIRE)--Merck KGaA, Darmstadt, Germany (MRK GY) announced today that it has entered into a global agreement with Pfizer Inc. (NYSE:PFE) to co-develop and co-commercialize MSB0010718C, an investigational anti-PD-L1 antibody currently in development by Merck KGaA, Darmstadt, Germany, as a potential treatment for multiple tumor types to accelerate the two companies' presence in immuno-oncology.

The asset will be developed as a single agent as well as in various combinations with Pfizer's and Merck KGaA, Darmstadt, Germany,'s broad portfolio of approved and investigational pipeline candidates. The two companies will also combine resources and expertise to advance Pfizer's anti-PD-1 antibody into Phase 1 trials. As part of the agreement, Merck KGaA, Darmstadt, Germany, will co-promote Pfizer's XALKORI, a medicine to treat non-small cell lung cancer, in the United States and several other key markets.

Karl-Ludwig Kley, Chairman of the Executive Board of Merck KGaA, Darmstadt, Germany, stated: "We live up to our promise to strengthen all three pillars of our business: Healthcare, Performance Materials and Life Science. After this year's acquisition of AZ Electronic Materials and the proposal to acquire Sigma-Aldrich, we have now turned the focus on healthcare. The agreement with Pfizer is a very important milestone in taking our pharma pipeline forward."

"Collaborating globally with Pfizer will allow us to benefit from the strengths and capabilities of both companies in immuno-oncology, further accelerating this promising asset in the race to address the needs of cancer patients across multiple tumor types. Up to 20 high priority immuno-oncology clinical development programs are expected to commence in 2015, including pivotal registration studies," continued Belén Garijo, President and Chief Executive Officer of the biopharmaceutical division of Merck KGaA, Darmstadt, Germany, and Executive Board Member Elect. "On top of that, the global alliance will enable Merck to gain an early entry into the US oncology market as well as to strengthen our existing oncology business in several other important global markets."

There are currently two clinical development programs underway evaluating the anti-PD-L1 antibody of Merck KGaA, Darmstadt, Germany. In a Phase 1 trial, more than 550 patients have been treated with MSB0010718C across multiple types of cancers. As part of the Analyst and Investor Day hosted by Merck KGaA, Darmstadt, Germany, on September 18, 2014, interim data were presented from the ongoing Phase 1 study demonstrating a complete response and partial responses in patients with non-small cell lung cancer and ovarian cancer. Additional data are expected to be presented at medical congresses in 2015. There is also an ongoing Phase 2 trial evaluating this antibody in patients with m-Merkel cell carcinoma, a rare form of skin cancer. For more information, please visit www.clinicaltrials.gov.

Under the terms of the agreement, Merck KGaA, Darmstadt, Germany, will receive an upfront payment of \$ 850 million (around € 680 million) and is eligible to receive regulatory and commercial milestone payments up to \$ 2.0 billion. Both companies will jointly fund all development and commercialization costs and all revenues obtained from selling any anti-PD-L1 or anti-PD-1 products generated from this collaboration will be shared

"Our strategic focus in the immuno-oncology space will be significantly enhanced through this global alliance, giving us the financial firepower to fully leverage the potential of our anti-PD-L1-compound" said Stefan Oschmann, Chief Executive Officer Pharma and Vice Chairman Elect of the Executive Board of Merck KGaA, Darmstadt, Germany. "The success of the anti-PD-L1 program and the value recognised by Pfizer is a clear reflection of the progress we have made on our R&D pipeline in recent years."

"This global alliance enables Pfizer and Merck KGaA, Darmstadt, Germany, to join forces and combine complementary strengths with the goal of meeting the needs of patients with multiple types of cancer," said Albert Bourla, Group President Vaccines, Oncology and Consumer Healthcare Businesses, Pfizer. "Immuno-oncology is a top priority for Pfizer. Combining this promising anti-PD-L1 antibody with Pfizer's extensive portfolio of small molecules and antibodies provides an opportunity to potentially broaden the use of immunotherapy for patients with cancer and rapidly expand our oncology business. In addition, this alliance enables us to significantly accelerate the timeframe of our development programs and

move into the first wave of potential immuno-oncology based treatment regimens."

Merck KGaA, Darmstadt, Germany, invites investors and analysts, as well as media and the general public to view and listen to a webcast of a live conference call at 2 p.m. Central European Time today.

Notes to editors

Further information for journalists including a digital press kit is here Interview with Belén Garijo, President and Chief Executive Officer of our biopharmaceutical division and Executive Board Member Elect Our company on Facebook and LinkedIn Photos and video footage can be found here All Merck KGaA, Darmstadt, Germany, press releases are distributed by e-mail at the same time they become available on the EMD Group Website. In case you are a resident of the USA or Canada please go to www.emdgroup.com/subscribe to register again for your online subscription of this service as our newly introduced geo-targeting requires new links in the email. You may later change your selection or discontinue this service.

About Merck KGaA, Darmstadt, Germany

Merck KGaA of Darmstadt, Germany, is a leading company for innovative and top-quality high-tech products in the pharmaceutical and chemical sectors. Its subsidiaries in Canada and the United States operate under the umbrella brand EMD. Around 39,000 employees work in 66 countries to improve the quality of life for patients, to further the success of customers and to help meet global challenges. The company generated total revenues of € 11.1 billion in 2013 with its four divisions: Biopharmaceuticals, Consumer Health, Performance Materials and Life Science Tools. Merck KGaA of Darmstadt, Germany is the world's oldest pharmaceutical and chemical company − since 1668, the name has stood for innovation, business success and responsible entrepreneurship. Holding an approximately 70 percent interest, the founding family remains the majority owner of the company to this day.

Filing	Data
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Not available

Contract

Not available.