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Bayer and Loxo Oncology to develop and commercialize two novel oncology therapies

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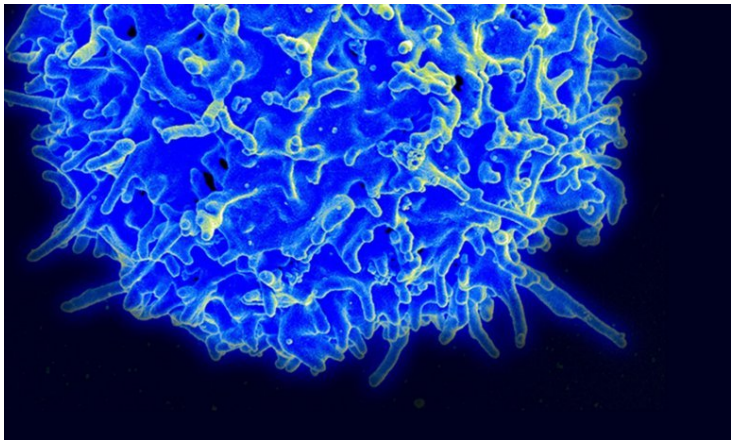

Life Science company Bayer has entered into an exclusive global collaboration with US based biopharma company Loxo Oncology for the development and commercialization of larotrectinib (LOXO-101) and LOXO-195.

Both compounds are being investigated in global studies for the treatment of patients with cancers harboring tropomyosin receptor kinase (TRK) gene fusions, which are genetic alterations across a wide range of tumors resulting in uncontrolled TRK signaling and tumor growth.

Under the terms of the agreement, Loxo Oncology will receive an upfront payment of USD 400 million and is eligible for USD 450 million in milestone payments upon larotrectinib regulatory approvals and first commercial sale events in certain major markets and an additional USD 200 million in milestone payments upon LOXO-195 regulatory approvals and first commercial sale events in certain major markets.

Bayer and Loxo Oncology will jointly develop the two products, larotrectinib and LOXO-195, and share development costs on a 50/50 basis. Bayer will lead ex-U.S. regulatory activities, and worldwide commercial activities. In the U.S., where Bayer and Loxo Oncology will co-promote the products, the parties will share commercial costs and profits on a 50/50 basis.

Loxo Oncology will remain responsible for the filing in the U.S. Bayer will pay Loxo Oncology tiered double-digit percentage royalties on future net sales outside of the U.S. and U.S. and ex-U.S. sales milestones totaling USD 500 million.

Dieter Weinand, Member of the Board of Management of Bayer AG and President of the Pharmaceuticals Division said, “The collaboration with Loxo Oncology represents another milestone in our endeavor to strengthen our oncology presence and underlines our commitment to this therapeutic area. Loxo Oncology’s very innovative approach complements Bayer’s oncology pipeline with highly differentiated compounds across different treatment modalities, which are being developed to make a meaningful difference for patients suffering from various types of cancer.”

Larotrectinib is an oral, potent and highly selective TRK inhibitor. LOXO-195 is a next-generation, selective TRK inhibitor capable of addressing potential mechanisms of acquired resistance that may emerge in patients receiving larotrectinib or multikinase inhibitors with anti-TRK activity.

Larotrectinib is currently the only selective TRK inhibitor in clinical development with the comprised clinical data set showing clinically meaningful and durable responses with an overall response rate of 75 percent, confirmed by an independent review committee, regardless of tumor type and age. The first filing for larotrectinib is planned in the U.S. in late 2017 or early 2018, with the EU filing expected in 2018.

Robert LaCaze, Executive Vice President and Head of the Oncology Strategic Business Unit at Bayer said, “We see great potential in larotrectinib and moreover the follow-on compound LOXO-195 which has the potential to provide additional benefit for patients who might progress on an initial TRK inhibition therapy. These agents have the potential to fullfil the promise of precision medicine, where tumor genetics rather than tumor site of origin define the treatment approach for patients.”

Jacob Van Naarden, chief business officer of Loxo Oncology said, “This is a transformational collaboration for the company as we prepare for commercialization. Bayer has a history of successful co-promotion efforts with emerging biopharmaceutical companies and we are confident that their oncology team has the global reach and expertise, including an existing field force dedicated to cancer, to complement our existing commercial plans. We look forward to working with Bayer and believe that together we can bring our TRK inhibitors to more patients more quickly.”