

Immunic AG gains exclusive, worldwide rights to promising drug development program with novel target for treatment of inflammatory bowel disease

IMU-856 is a new oral treatment option for ulcerative colitis and Crohn's disease

Daiichi Sankyo Co., Ltd. granted Immunic AG an exclusive option to in-license the drug development program when entering phase 1 clinical development

IMU-856 uses an undisclosed new target and mode of action for the treatment of IBD which is complementary to the Immunic portfolio and the team's expertise

IMU-856 compound and target are protected by worldwide patents yet unpublished

Planegg-Martinsried, Germany, November 5th, 2018 – Immunic AG (Immunic Therapeutics), a clinical stage biotech company in Martinsried near Munich, Germany, today announced that it has entered into an agreement with Daiichi Sankyo Co., Ltd. (hereinafter, Daiichi Sankyo) granting Immunic the exclusive right to license a group of compounds, designated by Immunic as IMU-856. The group of compounds uses a new pharmaceutical target based on animal models and promises an innovative way to a potentially disease-modifying treatment of inflammatory bowel disease (IBD). This development program also contains an orally available drug lead compound that is currently undergoing formal toxicology assessment in preparation of first human use. Immunic will be responsible for all further development as well as for all clinical development activities.

Daiichi Sankyo will receive a one-time option execution payment as well as a range of milestone payments and royalties.

"We are very excited that Daiichi Sankyo selected the Immunic team as their partner to take over the future development of this unique drug candidate," comments Dr. Daniel Vitt, CEO of Immunic AG. "During the last two years, we reviewed multiple therapeutic products in the field of IBD and we are convinced that the disease-modifying concept of IMU-856 offers outstanding new therapeutic potential for patients suffering from ulcerative colitis and Crohn's disease."

Dr. Takashi Fukuoka, Head of Venture Science Laboratories (VSL) at Daiichi Sankyo, says: "We are delighted that Immunic takes over development responsibility for IMU-856 which was developed by Daiichi Sankyo VSL researchers. We recognize Immunic AG as a leading expert for IBD and the underlying technology of the target and we are convinced that IMU-856 has the highest chance of success in the hands of the Immunic team."

"This product offers unique potentially disease-modifying properties and will act in a way that is very different from all currently available therapies. Most therapies for IBD patients act by unintentionally decreasing the body's immune surveillance resulting in higher risks regarding for example infections or malignant tumors," explains Dr. Andreas Mühler, MD, Chief Medical Officer at Immunic AG. "There is a high need for effective therapies in IBD that offer long-term relapse-free treatment of IBD patients while maintaining the full immune competency. The Immunic team believes that IMU-856 due to its innovative mechanism of action may be developed into such new option for IBD patients."

IMU-856: Highly selective potentially disease-modifying IBD drug candidate

The innovative IMU-856 emerged from Daiichi Sankyo, a team of outstanding scientists focused on finding and developing new and yet unexplored targets using innovative concepts in drug discovery and development. IMU-856 is the result of genetic target validation and *in vivo* proof-of-concept studies in relevant models for the disease. Daiichi Sankyo succeeded in identifying extremely target selective and potent molecules from a systematic screening and by using a structure-based design approach. Since IBD is not an indication area of commercial interest for Daiichi Sankyo, the company decided to out-license this exciting compound at the late preclinical stage.

IMU-856 is currently in advanced pre-clinical testing. Immunic plans to start a first clinical phase 1 trial in healthy volunteers in the near future.

The molecule is part of a full series of molecules using a new and potentially disease-modifying mode of action for the treatment of IBD. The product and the concept are protected by several patent applications and know-how developed at Daiichi Sankyo.

Synergies in the Immunic pipeline

This agreement gives Immunic access to a new product with strong synergies to its current development pipeline, namely

IMU-838, which is in clinical phase 2 testing in patients with ulcerative colitis. IMU-838 is an orally available, next-generation selective immune modulator and inhibits an enzyme called “dihydroorotate dehydrogenase” (DHODH) which plays a key role in the metabolism of activated lymphocytes while leaving other immune cells largely unaffected and allows the immune system to stay functioning, e.g. in fighting infections. “Targeting acute inflammation with IMU-838 and combining this concept with the complementary mode of action of IMU-856 could lead to a big step in the therapy of IBD beyond the current state-of-the-art in this disease,” commented Dr. Hella Kohlhof, CSO of Immunic AG.

About Immunic

Immunic is the specialist for selective oral drugs in immunology. As a clinical stage company, Immunic delivers clinical proof-of-concept for best-in-class therapies of chronic inflammatory diseases. The company’s three development programs include orally available, small molecule inhibitors of DHODH (IMU-838 program), an inverse agonist of ROR γ t (IMU-935 program) and IMU-856 (undisclosed novel target) relevant to diseases such as ulcerative colitis, Crohn’s disease and psoriasis. The final aim is to develop these oral drug candidates to clinical proof of concept. The company was founded in 2016 with headquarters in Planegg-Martinsried near Munich, Germany, and is privately held and supported by several renowned sector investors. For further information, please see:

www.immunic-therapeutics.com.

About Daiichi Sankyo

Daiichi Sankyo Group is dedicated to the creation and supply of innovative pharmaceutical products to address diversified, unmet medical needs of patients in both mature and emerging markets. With over 100 years of scientific expertise and a presence in more than 20 countries, Daiichi Sankyo and its 15,000 employees around the world draw upon a rich legacy of innovation and a robust pipeline of promising new medicines to help people. In addition to a strong portfolio of medicines for hypertension and thrombotic disorders, under the Group’s 2025 Vision to become a “Global Pharma Innovator with Competitive Advantage in Oncology,” Daiichi Sankyo research and development is primarily focused on bringing forth novel therapies in oncology, including immuno-oncology, with additional focus on new horizon areas, such as pain management, neurodegenerative diseases, heart and kidney diseases, and other rare diseases. For more information, please visit: www.daiichisankyo.com.

About IMU-856

IMU-856 is a newly developed and orally available small molecule aiming at a yet undisclosed target, which is known to be prominently involved in the initiation of inflammatory bowel-diseases like ulcerative colitis and Crohn’s disease and in the process of disease relapse. The mechanism of action does not primarily target immune functions and it should therefore maintain full immune surveillance for patients. IMU-856 is currently in advanced preclinical testing and clinical phase 1 is planned to commence in the near future.

About IMU-838

IMU-838 is an orally available, next-generation selective immune modulator. IMU-838 targets intracellular metabolism of activated immune cells by inhibition of the enzyme “dihydroorotate dehydrogenase” (DHODH). With this mode of action, IMU-838 is a potent inhibitor of Th17 and Th1 subsets of T-lymphocytes as well as activated B-cells without potentially increasing the risk of viral infections. IMU-838 was successfully tested for PK and safety in two Phase 1 studies. IMU-838 is currently tested in a clinical Phase 2 trial (CALDOSE-1) in patients with ulcerative colitis. Immunic is planning to start a further Phase 2 clinical trial in Crohn’s disease (CD) and multiple sclerosis.

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