



PRESS RELEASE

Servier and ILTOO Pharma sign a license option agreement for the clinical development and commercialization of low-dose interleukin-2 for the treatment of autoimmune diseases

This partnership paves the way for a promising therapy for autoimmune diseases with major unmet medical needs, with lupus as a priority target

31 May 2017 – Servier and ILTOO Pharma announced today the signature of an exclusive license option agreement for the development and commercialization of the ILT-101 drug candidate (low-dose interleukin-2) for the treatment of autoimmune diseases, with systemic lupus erythematosus (SLE) as the first target indication. This option shall be triggered in 2018 when the results of the ongoing phase 2 clinical study in SLE patients are known.

Under the terms of the agreement, and depending on the results of this international phase 2 trial in patients suffering from moderate to severe SLE, Servier may decide to exercise the license option to develop and commercialize ILT-101 (low-dose IL-2) worldwide in the treatment of autoimmune diseases, except for the United States and Japan, where ILTOO Pharma retains exclusive rights. In return for the grant of this option, ILTOO Pharma will receive €8 million immediately, and subsequent payments comprising one upfront payment upon exercise of the option, plus development and sales milestones worth a total of €200 million. The agreement also provides for double-digit royalty payments on future sales.

A French academic research team from AP-HP hospital authority and Sorbonne Universities led by Prof. Klatzmann, the co-founder of ILTOO Pharma, made the original discovery that low-dose IL-2 represents a promising therapy for multiple autoimmune diseases. These pathologies are caused by a shortage of regulatory T cells, a population of immune system cells that protects our tissue from attacks by other cell sub-populations from within our own immune system. Low-dose IL-2 stimulates the regulatory T cells, restoring this protection. The vast therapeutic potential of low-dose IL-2 was presented recently by Prof. Klatzmann and Prof. Abbas in a prestigious medical review¹. This approach has the unique advantage of overcoming immune system dysregulation through the administration of a natural therapeutic protein. In contrast, the conventional immunosuppressive approach blocks the immune system at large, triggering potentially serious side effects in certain cases. Servier has decided to team up with ILTOO Pharma to deliver the benefits of these advances to patients.

“The approach taken by ILTOO Pharma’s team persuaded us of ILT-101’s potential to treat highly debilitating diseases, for which no effective treatment exists today”, commented Patricia Belissa-Mathiot, Head of Servier’s R&D department for immune-inflammatory diseases. “Our original

¹ *The promise of low-dose interleukin-2 therapy for autoimmune and inflammatory diseases; Natures Reviews Immunology; Volume 15, May 2015*



corporate structure of governance by a non-profit foundation enables us to invest in innovative projects in our areas of expertise for the benefit of patients.”

“This partnership with Servier represents a major source of operational support for ILTOO Pharma and provides further evidence of the potential for our novel therapeutic approach”, commented Jérémie Mariau, Chief Executive Officer of ILTOO Pharma. “It opens up fresh prospects for our Company and our products, especially in the United States and Japan, with the acceleration of the development and market launch of ILT-101. Lastly, the agreement reflects the effectiveness of the innovation process initiated and patented by the university, then licensed to ILTOO Pharma and now supported by a French pharma group with a global footprint.”

Autoimmune diseases include a wide range of conditions, such as diabetes, multiple sclerosis and lupus, and are today the third-largest cause of mortality/morbidity in developed countries. They are caused by the dysregulation of the immune system, whereby it attacks its own organs and tissue via so-called effector T cells, which are normally controlled by the regulatory T cells. In all autoimmune diseases, the balance between regulatory T cells and effector T cells is disrupted. The low-dose IL-2 therapeutic approach helps to restore the balance between these two cell populations. Specifically, it increases the number of regulator cells, which control the autoimmune response.

Lupus is an autoimmune disease most common in women aged between 15 and 40 years old, which can affect various parts of the body, including joints, skin, the kidneys, and heart. The frequency of lupus varies between one case in 1,200 and one case in 5,800 people, or the equivalent of around 270,000 patients in Europe. It is a chronic debilitating condition, which may progress towards highly severe forms.

About Servier

Servier is an international pharmaceutical company governed by a non-profit foundation, with its headquarters in France (Suresnes). With a strong international presence in 148 countries and a turnover of 4 billion euros in 2016, Servier employs 21,000 people worldwide. Entirely independent, the Group reinvests 25% of its turnover (excluding generic drugs) in research and development and uses all its profits for development. Corporate growth is driven by Servier’s constant search for innovation in five areas of excellence: cardiovascular, immune-inflammatory and neuropsychiatric disease, oncology and diabetes, as well as by its activities in high-quality generic drugs.

Becoming a key player in the fight against immune-inflammatory disease is part of Servier’s long-term strategy. Servier wishes to bring innovative therapeutic solutions to patients suffering from these often highly debilitating pathologies. Its research focuses on lupus, Gougerot-Sjögren syndrome and scleroderma, for which no cure exists. This goal will be reached by establishing partnerships all over the world, in order to accelerate the marketing of innovative drugs with high added value for patients.

More information: www.servier.com

About ILTOO

ILTOO Pharma is a French biotech company with its headquarters in Paris dedicated to the development of immunotherapies for the treatment of autoimmune and inflammatory diseases. ILTOO Pharma possesses a deep expertise relating to the mechanisms of regulation of the immune system in particular on the role of regulatory T lymphocytes (Tregs). The company is a global pioneer in this field. ILTOO Pharma concentrates its research efforts on two pathologies with a high unmet medical need, namely systemic lupus erythematosus and type 1 diabetes. The therapeutic potential of the technology deployed by ILTOO Pharma allows it to consider the treatment of many other autoimmune and inflammatory diseases.

More information: www.iltoopharma.fr

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