



Press Release

Lead Pharma Announces Start of Phase I Clinical Trials with SAR441169 Candidate Treatment for Psoriasis

- Sanofi, Lead Pharma's collaborative partner in the development of SAR441169, successfully initiated first human dosing with this novel ROR γ t Inverse Agonist candidate treatment
- For Lead Pharma this represents a fourth payable milestone in the SAR441169 collaboration with Sanofi

Oss, The Netherlands March 21, 2019 – Lead Pharma, a pharmaceutical company developing innovative medicines for the treatment of immunological and oncological indications, today announced that it has achieved a fourth milestone under its license & collaboration agreement with Sanofi, triggering an undisclosed milestone payment. The milestone payment is linked to Sanofi's dosing of the first human volunteers in a Phase I clinical trial of SAR441169, a novel inverse agonist of the nuclear hormone receptor ROR γ t.

"We are excited to have reached this important milestone in our collaboration with Sanofi. This is Lead Pharma's first compound to enter the clinic, representing a significant next step in the realization of our growth ambitions", said Frans van den Berg, Chief Executive Officer of Lead Pharma.

"The progression into clinical development with this project is great validation of our strength in innovative drug discovery, which is also being applied to our internal pipeline projects", added Arthur Oubrie, Chief Scientific Officer of Lead Pharma.

Steve Pascoe, MD, Head of Immuno-Inflammation Development at Sanofi Genzyme, commented: *"With the initiation of clinical investigations in humans, this promising ROR γ t inverse agonist moves one step closer to advancing psoriasis treatment. This is not only exciting for psoriasis sufferers but could also hold hope for others since this candidate compound works on the interleukin-17 inflammatory pathway, known to be critical in the treatment of a range of chronic autoimmune diseases."*

This Phase I study by Sanofi will assess the tolerability, safety, and pharmacokinetics of single and ascending once daily oral dosing of SAR441169 in healthy adult subjects, and is aimed at gaining early evidence on effectiveness after four weeks of oral treatment in patients with moderate to severe psoriasis.

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About Autoimmune Disorders

A wide range of human diseases are driven by deregulated immune function. These immune-mediated disorders include joint diseases such as rheumatoid arthritis and inflammatory bowel diseases such as ulcerative colitis and Crohn's disease. Often, these diseases are characterized by inappropriate activation of molecules termed cytokines, which are important mediators of normal immune function. When inappropriately activated, these powerful molecules can cause severe damage to multiple body systems. Symptoms of immune-mediated diseases range from mild skin rashes to severe organ failure to death. In addition to the significant suffering of patients, the socioeconomic burden of just rheumatoid arthritis has been estimated at approximately \$40 billion in the U.S. alone (cf. J Rheumatol 2011; 88; 55-61; <http://www.jrheum.org/content/88/55>).

About RORyt

The nuclear receptor retinoic acid receptor-related orphan receptor gamma, also known as RORyt, is a key regulator of the cytokine immune pathway, which leads to the differentiation of T cells to a pro-inflammatory subtype of T helper cells called Th17. RORyt drives the production of key pro-inflammatory proteins, including interleukin (IL)-17A, IL-17F and the receptor for IL-23. In the last years, several clinical studies have validated the critical role of the IL-17 pathway in chronic autoimmune-related inflammation. Recent findings have demonstrated that the biological function of RORyt can be moderated with small molecules and have advanced this target to the cutting edge of drug discovery.

About Lead Pharma

Lead Pharma is a pharmaceutical company focusing on the discovery and development of innovative medicines for the treatment of autoimmune diseases and cancer. Lead Pharma's drug discovery engine combines medicinal, structural, and computational chemistry with molecular pharmacology, cell and tissue-based pharmacology. Lead Pharma has a pipeline of first- and best-in-class small molecule drugs in various stages of drug discovery and pre-clinical development.

Lead Pharma is a privately owned company based in Oss, the Netherlands. Shareholders in the company include BOM Brabant Ventures, Oost NL, Biox Biosciences and Waterman ventures.

About the license & collaboration agreement

In February 2015, Lead Pharma and Sanofi entered into a license & research collaboration agreement to discover, develop and commercialize small molecule therapies directed against RORyt. Lead Pharma is eligible to receive milestone payments and is entitled to receive royalty payments on global sales from any resulting products.

For more information visit: www.leadpharma.com

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Contact:

Media Inquiries:

LifeSpring Life Sciences Communication, Amsterdam

Leon Melens

Tel.: +31 (0) 6 538 16 427

Lmelens(at)lifespring.nl

Company Inquiries:

Lead Pharma Holding B.V.

Frans van den Berg MSc MBA

Chief Executive Officer

Tel.: +31 412 782999

frans.vandenberg@leadpharma.com