



## Lead Pharma to Partner with Sanofi on Development of Treatments for Autoimmune Diseases

*- R&D collaboration and license agreement may yield potential first-in-class oral anti-ROR gamma (t) therapies*

**Nijmegen, Feb. 18, 2015** – Lead Pharma, a pharmaceutical company developing innovative medicines for the treatment of autoimmune diseases and cancer, today announced that it has entered into a research collaboration and license agreement with Sanofi to discover, develop and commercialize small molecule therapies directed against the nuclear hormone receptor ROR gamma (t) to treat a broad range of autoimmune disorders, including common diseases such as rheumatoid arthritis and inflammatory bowel disease.

Researchers have identified 80 to 100 different autoimmune disorders and suspect at least an additional 40 diseases of being driven by immune function. These diseases are chronic and can be life-threatening.

“With an estimated 25 million people in the U.S. alone affected by such a broad range of autoimmune disorders, a significant unmet medical need exists in the area, and anti-ROR gamma (t) therapies represent a ground-breaking opportunity that we are eager and motivated to pursue through our collaboration with Lead Pharma,” said Christian Antoni, Vice President and Head of the Immunology & Inflammation Franchise, Research and Development, Sanofi. “Lead Pharma’s innovative capabilities and productivity, exemplified by the ROR gamma (t) program, make them ideal partners for Sanofi in this area of drug discovery.”

“We are absolutely delighted to start a relationship with Sanofi, a collaboration that builds on the culture of scientific excellence fostered by both companies,” said Ad van Gorp, co-founder and Chief Executive Officer of Lead Pharma.

Arthur Oubrie, Chief Scientific Officer of Lead Pharma, added: “We are excited to combine our own excellence in structure-based drug design, medicinal chemistry and target-based pharmacology with the fire power of Sanofi in drug discovery, development and commercialization.”

Under the terms of the agreement, Lead Pharma will receive an upfront payment and is eligible to receive research, development, regulatory and commercial milestone payments. Further details of the financial terms have not been disclosed. Sanofi is responsible for clinical development and will have worldwide marketing and commercialization rights to any products that may be developed as a result of the collaboration. Lead Pharma is entitled to receive royalty payments on global sales from any such products.

### **About Autoimmune Disorders**

A wide range of human diseases are driven by deregulated immune function. There are hundreds of immune-mediated disorders that include joint diseases such as rheumatoid arthritis, 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. Manifestations 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.<sup>1</sup>

### **About ROR gamma (t)**

The nuclear receptor retinoic acid receptor-related orphan receptor gamma, also known as ROR gamma (t), 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. ROR gamma (t) 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 showing that the biological function of ROR gamma (t) can be moderated with small molecules have advanced this target to the cutting edge of drug discovery.

### **About Sanofi**

Sanofi, an integrated global healthcare leader, discovers, develops and distributes therapeutic solutions focused on patients' needs. Sanofi has core strengths in the field of healthcare with seven growth platforms: diabetes solutions, human vaccines, innovative drugs, and consumer healthcare, emerging markets, animal health and the new Genzyme. Sanofi is listed in Paris (EURONEXT: SAN) and in New York (NYSE: SNY).

### **About Lead Pharma**

Lead Pharma is a biopharmaceutical 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. Thereby, the company aims to identify first and / or best-in-class small molecule drugs. Based in Nijmegen and Oss, the Netherlands, Lead Pharma is privately owned and is financed by Biox Biosciences, Participatiemaatschappij Oost Nederland N.V. (PPM Oost), Life Sciences & Health Fund B.V., and Technostartersfonds Zuid Nederland B.V. For more information visit: [www.leadpharma.com](http://www.leadpharma.com)

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### **References**

<sup>1</sup> J Rheumatol 2011;88;55-61; <http://www.jrheum.org/content/88/55>