



## Sanofi and Lead Pharma to Develop Treatments for Autoimmune Diseases

*- R&D collaboration may yield potential first-in-class oral ROR gamma t therapies -*

**Paris - February 18, 2015** - [Sanofi](#) announced today that it has entered into a research collaboration and license agreement with Dutch biotech [Lead Pharma](#) to discover, develop and commercialize small-molecule therapies directed against the nuclear hormone receptors called ROR gamma t to treat a broad range of autoimmune disorders, including rheumatoid arthritis, psoriasis and inflammatory bowel disease, which are among the most common.

*“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 & Development, Sanofi. *“At Sanofi, we believe networked innovations - working collaboratively across science sectors - is the most effective way to bring meaningful new therapies to patients. To this end, 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.”*

Under the terms of the agreement, Sanofi and Lead Pharma will collaborate during the early phase of research and development with a goal of identifying drug candidates and beginning human trials within 3-4 years. Lead Pharma will receive an upfront payment and is eligible to receive research, development, regulatory and commercial milestone payments. Sanofi will be responsible for clinical development and 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. Further details of the financial terms have not been disclosed.

### 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 to 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 or ROR gamma (t), is a key regulator of the cytokine immune pathway, interleukin (IL)-17, which lead to the differentiation of T cells to a pro-inflammatory subtype of T helper cells called

Th17. As such, ROR gamma (t) drives the production of key pro-inflammatory proteins including IL-17A, IL-17F and the receptor for IL-23. Clinical studies validating the critical role of the IL-17 pathway in chronic autoimmune-related inflammation is growing. Recent findings that show the biological function of ROR gamma (t) can be moderated with small molecules have propelled 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 started its activities at the Agri Food Health Innovation Centre and is currently located at both the NovioTech Campus in Nijmegen and the Pivot Park in Oss, the Netherlands. The company aims to discover and develop first or best in class small molecule drugs 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 to select and advance the most promising molecules. Lead Pharma is a privately owned drug discovery company 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)

### Forward-Looking Statements

*This press release contains forward-looking statements as defined in the Private Securities Litigation Reform Act of 1995, as amended. Forward-looking statements are statements that are not historical facts. These statements include projections and estimates and their underlying assumptions, statements regarding plans, objectives, intentions and expectations with respect to future financial results, events, operations, services, product development and potential, and statements regarding future performance. Forward-looking statements are generally identified by the words "expects", "anticipates", "believes", "intends", "estimates", "plans" and similar expressions. Although Sanofi's management believes that the expectations reflected in such forward-looking statements are reasonable, investors are cautioned that forward-looking information and statements are subject to various risks and uncertainties, many of which are difficult to predict and generally beyond the control of Sanofi, that could cause actual results and developments to differ materially from those expressed in, or implied or projected by, the forward-looking information and statements. These risks and uncertainties include among other things, the uncertainties inherent in research and development, future clinical data and analysis, including post marketing, decisions by regulatory authorities, such as the FDA or the EMA, regarding whether and when to approve any drug, device or biological application that may be filed for any such product candidates as well as their decisions regarding labelling and other matters that could affect the availability or commercial potential of such product candidates, the absence of guarantee that the product candidates if approved will be commercially successful, the future approval and commercial success of therapeutic alternatives, the Group's ability to benefit from external growth opportunities, trends in exchange rates and prevailing interest rates, the impact of cost containment policies and subsequent changes thereto, the average number of shares outstanding as well as those discussed or identified in the public filings with the SEC and the AMF made by Sanofi, including those listed under "Risk Factors" and "Cautionary Statement Regarding Forward-Looking Statements" in Sanofi's annual report on Form 20-F for the year ended December 31, 2013. Other than as required by applicable law, Sanofi does not undertake any obligation to update or revise any forward-looking information or statements.*

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### References

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