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### **GENFIT: Successful identification of ROR $\gamma$ t inverse agonists as candidates for regulatory pre-IND studies**

- **GENFIT has reached a key milestone in its research program focused on the development of novel ROR $\gamma$ t inverse agonists**
- **In addition to its strong position in metabolic diseases and fibrosis, GENFIT strengthens its pipeline with products that target the immune system**

**Lille (France), Cambridge (Massachusetts, United States), September 23, 2016** – GENFIT (Euronext: GNFT - ISIN: FR0004163111), a biopharmaceutical company at the forefront of developing therapeutic and diagnostic solutions in metabolic and inflammatory diseases, that notably affect the liver or the gastrointestinal system, today announced the expansion of its product pipeline with the integration of novel ROR $\gamma$ t inverse agonists.

Diverse chemical series of ROR $\gamma$ t inverse agonists were designed and optimized for the last three years at GENFIT as part of ambitious large-scale efforts to diversify the portfolio of GENFIT's proprietary drug candidates for the treatment of autoimmune, inflammatory and fibrotic diseases. We report today on validation of drug candidates that will enter the path of regulatory pre-IND studies. These candidates are highly potent and selective against other members of the ROR nuclear receptor family, and interfere with IL-17 production in human blood leukocytes.

Potential therapeutic application areas for ROR $\gamma$ t inverse agonists cover a wide spectrum of dermatologic, respiratory, or systemic diseases. The physicochemical properties of our ROR $\gamma$ t inverse agonists are compatible with classical methods of skin delivery, and as a first approach, it is envisaged to develop a topical formulation for applications in dermatologic diseases such as psoriasis. GENFIT is open to forge mutually beneficial collaborations with companies that have an established franchise in dermatology in order to advance this program to the clinic in an efficient way.

In parallel, other approaches for inhalation and oral delivery are being optimized, which will provide additional opportunities in respiratory and systemic diseases respectively.

**Jean-François Mouney, Chairman & CEO of GENFIT**, said: *"After several years of dedicated research, and thanks to our strong expertise in nuclear receptors, we are pleased to have reached a key step towards the clinical development of ROR $\gamma$  inverse agonists. We are confident that these novel compounds have the potential to open new therapeutic strategies in several immune diseases that involve ROR $\gamma$ t."*



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**Professor Bart Staels, Chairman of the Scientific Advisory board of GENFIT,** commented: *"Over the past few years, Th17 cells that rely on ROR $\gamma$ t expression have received a lot of attention due to their essential role in immune system homeostasis and pathology. In addition to IL-17, Th17 cells also express other proinflammatory cytokines. In this context, targeting the Th17 cell lineage by antagonizing ROR $\gamma$ t activity may give superior results as compared to blocking a single effector cytokine with an antibody."*

### About ROR $\gamma$ t:

ROR $\gamma$ t is a lineage commitment factor for several classes of leukocytes that produce and secrete interleukin 17 (IL-17), an important regulatory factor in the immune system. Dysregulation and pathologic roles of IL-17 signaling were reported in many systemic diseases that concern hundreds of millions of patients around the world, including but not limited to chronic inflammatory and autoimmune diseases such as psoriasis, multiple sclerosis, rheumatoid arthritis, COPD, neutrophilic asthma, fibrotic chronic liver diseases and certain cancers.

ROR $\gamma$ t is recognized today as an attractive therapeutic target among the nuclear receptors and it is capturing the interest of an increasing number of pharmaceutical companies.

### About GENFIT:

GENFIT is a biopharmaceutical company focused on the discovery and development of drug candidates in areas of high unmet medical needs corresponding to a lack of suitable treatment and an increasing number of patients worldwide. GENFIT's R&D efforts are focused on bringing new medicines to market for patients with metabolic, inflammatory, autoimmune and fibrotic diseases, that affect the liver (such as NASH – Nonalcoholic steatohepatitis) and more generally the gastrointestinal arena. GENFIT's approach combines novel treatments and biomarkers. Its lead proprietary compound, Elafibranor, is currently in a Phase 3 study. With facilities in Lille, France, and Cambridge, MA (USA), the Company has approximately 110 employees. GENFIT is a public company listed in compartment B of Euronext's regulated market in Paris (Euronext: GNFT - ISIN: FR0004163111). [www.genfit.com](http://www.genfit.com)

### Forward Looking Statement / Disclaimer:

This press release contains certain forward-looking statements. Although the Company believes its expectations are based on reasonable assumptions, these forward-looking statements are subject to numerous risks and uncertainties, which could cause actual results to differ materially from those expressed in, or implied or projected by, the forward-looking statements. These risks and uncertainties include among other things, the uncertainties inherent in research and development, including related to biomarkers, progression of, and results of clinical data from, the RESOLVE-IT trial, review and approvals by regulatory authorities, such as the FDA or the EMA, regarding in particular, Elafibranor in NASH and PBC, as well as other indications, and biomarkers, the success of any inlicensing strategies, the Company's continued ability to raise capital to fund its development, as well as those discussed or identified in the Company's public filings with the AMF,



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including those listed under Section 4 "Risk Factors" ("Facteurs de Risque") of the Company's 2015 Registration Document registered with the French market authority (AMF) on June 29, 2016 under n° R.16-062, which is available on GENFIT's website ([www.genfit.com](http://www.genfit.com)) and on the website of the AMF ([www.amf-france.org](http://www.amf-france.org)). Other than as required by applicable law, the Company does not undertake any obligation to update or revise any forward-looking information or statements.

This press release and the information contained herein do not constitute an offer to sell or a solicitation of an offer to buy or subscribe to shares in GENFIT in any country. This press release has been prepared in both French and English. In the event of any differences between the two texts, the French language version shall supersede.

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