



## GENFIT Signs an Agreement for the Enhancement of Medical Knowledge & Landscape of NASH Research

- › **NASH Registry Project**, a long-term agreement between GENFIT and the *Pinnacle Clinical Research Center* directed by Dr. Stephen Harrison, San Antonio, TX, USA
- › Database in which NAFLD patients are followed prospectively to gain information on co-morbidities historically linked to NAFLD/NASH, via a collaboration between Endocrine/Diabetes Centers and Hepatology Centers, and with acquisition of de-identified patient data by GENFIT
- › During 2016 AASLD Annual Meeting, GENFIT will provide information on several other topics via company webcast, poster, and oral presentations

**Lille (France), Cambridge (Massachusetts, United States), November 10, 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 that the company has signed an agreement for a **NASH Registry Project** with *Pinnacle Clinical Research Center*, directed by Dr. Stephen Harrison, San Antonio, TX, USA.

This agreement is an important step taken to improve the NASH patient referral process between the different specialties involved in this pathology: endocrinology, diabetology, gastroenterology and hepatology. Linking Hepatology Research Centers with Endocrine Clinics indeed provides for a unique opportunity to target the patient at greatest risk of NASH. These same patients are likely to carry the greatest risk for moderate to advanced fibrosis.

Under this agreement, a set of NASH parameters will be provided to each site, that will be used to screen for patients that may qualify for the NASH Registry.

The data generated will be used to inform the medical community about overall prevalence, natural history of the disease, as well as progression of co-morbidities. As such it will further increase the global understanding of NASH and its comorbidities in patients at risk.

GENFIT will be granted access to the collected data, provided that the release of the de-identified data has been approved by the local ethics committee and patients.

**Dr. Stephen Harrison, Pinnacle Clinical Research, San Antonio, TX, USA, and Member of the international steering committee of the Phase 3 RESOLVE-IT study in NASH** commented: *"This agreement is a first step of what will in principle become a large patient registry program in NASH. It is really exciting to have such framework now fully set-up, because it means we are in a position to start collecting essential patient data that will complement clinical trial data in a very useful and valuable way for the whole scientific and medical community. As a hepatologist caring for NASH patients on a regular basis, I'm particularly well aware of the need for a multidisciplinary approach to address all challenges related to this emerging but silent disease. In this respect, a well designed form of collaboration – between hepatologists, gastroenterologists,*



*endocrinologists and diabetologists who treat patients at risk – is certainly a key success factor in the fight against this disease. This is the reason why we have decided to set-up Pinnacle's NASH Registry, and also the reason why we are now very happy to get the support of GENFIT to develop this initiative one step further."*

**Sophie Méguien, Chief Medical Officer (CMO) of GENFIT** commented: *"It is important for us to take such concrete steps in relation to the patient referral process, because NASH involves different specialties. We all know that NASH is much more than a simple liver disease and this is why, today, all hepatologists who have been working on the disease for a long time are convinced of the need to collaborate with diabetologists and endocrinologists, given the direct correlation between the cardiometabolic condition of NASH patients and the state of their liver. But once you have said this, there is still a lot to do to make things happen. This is why we wanted to contribute to a program like Pinnacle's NASH Registry, that involves highly relevant and cross-disciplinary experts. The whole medical community will undoubtedly be able to capitalize on this work in the near future. Note that this collaboration is perfectly aligned with other initiatives taken by GENFIT around disease awareness."*

#### **About GENFIT webcast at 2016 AASLD Annual Meeting:**

GENFIT's investor and analyst event will be webcasted on **Monday, November 14 at 1:00 p.m. E.T. from Boston, MA, USA**. The live event will be accessible via the investor page on the company website ([www.genfit.com](http://www.genfit.com)).

It will also be accessible via: <https://www.webcaster4.com/Webcast/Page/359/18404>

A replay will be archived for 7 days and available on [www.genfit.com](http://www.genfit.com).

#### **About GENFIT participation at 2016 AASLD Annual Meeting:**

Five abstracts were proposed by GENFIT and accepted by the AASLD committee.

- **Friday, November 11:** "Assessment of serum levels of Chitinase-3-like protein 1 (CHI3L1) improves identification of the NASH patients at risk who should be treated", A. Sanyal *et al.* (Abstract 658)
- **Saturday, November 12:** "ALT as a non-invasive biomarker of histological response to pharmacotherapy in NASH patients: insights from the elafibranor GOLDEN-505 trial", V. Ratziu *et al.* (Abstract 1154)
- **Sunday, November 13:** "Improvement in NASH histological activity highly correlates with fibrosis regression", V. Ratziu *et al.* (Abstract LB-37)
- **Sunday, November 13:** "Comparison of liver pathology in three rodent NASH models to that observed in human NASH patients", F. Texier *et al.* (Abstract 1598)
- **Oral session – Monday, November 14, 3:15pm -3:30pm:** "Validation of mir-34a, mir-122 and mir-200a as biomarkers for identification of NASH patients eligible for treatment", S. Francque *et al.* (Abstract LB-2)



GENFIT will host 3 events:

- **Analyst/investor event – Monday November 14, 1:00pm -2:00pm:** with the participation of four international experts (Dr. Vlad Ratziu, France, Dr. Stephen A. Harrison, USA, Dr. Joel Lavine, USA, Dr. Velimir Luketic, USA);
- **Scientific Advisory Board dedicated to biomarkers in NASH;**
- **Scientific Advisory Board on fibrosis.**

In addition,

- **GENFIT will host a booth (#335);**
- **Sophie Mégnien, CMO of GENFIT, will co-chair a working group of the Liver Forum.**

#### About elafibranor:

Elafibranor is GENFIT's lead pipeline product. Elafibranor is an oral once-daily treatment, and a first-in-class drug acting via dual peroxisome proliferator-activated alpha/delta pathways developed to treat, in particular, nonalcoholic steatohepatitis (NASH). Elafibranor is believed to address multiple facets of NASH, including inflammation, insulin sensitivity, lipid/metabolic profile, and liver markers.

#### About NASH:

"NASH", or nonalcoholic steatohepatitis, is a liver disease characterized by an accumulation of fat (lipid droplets), along with inflammation and degeneration of hepatocytes. The disease is associated with long term risk of progression to cirrhosis, a state where liver function is diminished, leading to liver insufficiency, and also progression to liver cancer.

#### About Pinnacle Clinical Research Center:

*Pinnacle Clinical Research Center* was founded by a group of San Antonio area physicians from multiple practices. San Antonio, and the surrounding areas within South Texas, has a high incidence of fatty liver disease. These gastroenterologists saw a need for a world class research center to address this unmet need. The center, headed by its Board of Directors and the Medical Director, Dr. Stephen Harrison, is strategically focused on liver disease.

#### 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 gastro-intestinal 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 and Paris, 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, including those listed under Section 7 "Main Risks and Uncertainties" of the Company's Half Year 2016 Business and Financial Report, 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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