



June 11, 2019

GENFIT: Cymabay Phase 2 data: read-across for RESOLVE-IT?

Dear investor,

In reaction to the confusion generated by Cymabay's Phase 2b announcement earlier today, we would like to bring to your attention a few important points:

- Reduction of liver fat content measured by MRI-PDFF or any other means is not considered by regulators as relevant for approval in NASH
- Approval is based on "NASH resolution without worsening of fibrosis" solely defined with "hepatocyte ballooning" and "lobular inflammation", through histological examination irrespective of steatosis evolution
- According to this definition, in a 52w Phase 2b trial, elafibranor achieved "NASH Resolution without worsening of fibrosis", and its on-going Phase 3 trial RESOLVE-IT will readout by year-end, after 72w, on the same regulatory endpoint
- Elafibranor (dual PPARa/d agonist) activates complementary pathways via alpha and delta (eg. inflammation), and it has shown positive activity on HbA1c, HDL, insulin sensitivity

As a reminder, we believe elafibranor is uniquely positioned in NASH with the potential to become the first monotherapy to be approved by the FDA and the EMA for "NASH resolution without worsening of fibrosis" (ballooning = 0; inflammation = 0 or 1). Phase 2b data published in Gastroenterology, by Ratziu, in May 2016, have shown elafibranor's unique potential to combine:

- efficacy on the regulatory endpoint, approved for Phase 3 trials, that is related to the underlying cause of disease progression to cirrhosis or cancer;
- improvement of the cardiometabolic risk profile (reduction of LDL and TG, increase of HDL, and improvement of insulin sensitivity);
- favorable safety and tolerability profile.

If the molecule's beneficial activity is confirmed in Phase 3 – the duration of which is 6 months longer than the Phase 2 – elafibranor would be ideally positioned to be prescribed as first line treatment in monotherapy against NASH and as backbone of future combination therapy.

It is also important to realize that while fat is playing a role during the onset of NASH, evolution of fat composition is more important than just fat quantity. In line with this, GENFIT has recently launched a Phase 2 trial to evaluate elafibranor's impact on hepatic lipid composition for NAFL.





INFORMATION NOTE

This communication contains certain forward-looking statements, including those within the meaning of the Private Securities Litigation Reform Act of 1995, with respect to Genfit, including, the potential of elafibranor to become the first monotherapy approved in NASH by the FDA and EMA, the positing of elafibranor as a monotherapy in NASH and as the backbone of future combination therapies, and well as the potential of our Phase 3 trial to produce similar results to our Phase 2b trial. Although the Company believes its expectations are based on the current expectations and reasonable assumptions of the Company's management, these forward-looking statements are subject to numerous known and unknown 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 safety, biomarkers, progression of, and results from, its ongoing and planned clinical trials, review and approvals by regulatory authorities of its drug and diagnostic candidates and the Company's continued ability to raise capital to fund its development, as well as those risks and uncertainties discussed or identified in the Company's public filings with the French Autorité des marchés financiers ("AMF"), and public filings and reports filed with the U.S. Securities and Exchange Commission ("SEC"). These forward-looking statements speak only as of the date of this communication. Other than as required by applicable law, the Company does not undertake any obligation to update or revise any forward-looking information or statements, whether as a result of new information, future events or otherwise.

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