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GENFIT Reports Full-Year 2019 Financial Results and Corporate Update

- **Topline interim results from Phase 3 clinical trial RESOLVE-IT expected by the end of May 2020**
- **Cash position of €277MM as of December 31, 2019 (vs €207MM as of December 31, 2018)**
- **Significant milestones achieved in 2019:**
 - **Release of full dataset from the successful Phase 2 clinical trial of elafibranor in PBC, leading to “Breakthrough Therapy” and “Orphan Drug” designations**
 - **Strategic partnership with Terns Pharmaceuticals for the development and commercialization of elafibranor in Greater China, and strategic R&D agreement (\$35MM upfront payment, and up to \$193MM in milestones payment)**
 - **Licensing agreement with LabCorp-Covance for NIS4™, a non-invasive diagnostic tool for the identification of NASH patients with fibrosis**
 - **Global offering and U.S. IPO on Nasdaq, raising gross proceeds totaling \$155MM**
 - **Change in governance and strengthening of US footprint**
- **Conference call scheduled for April 9, 2020 at 8:00am EDT / 14:00 CEST**

Lille (France), Cambridge (Massachusetts, United States), April 8, 2020 – GENFIT (Nasdaq and Euronext: GNFT), a late-stage biopharmaceutical company dedicated to the discovery and development of innovative therapeutic and diagnostic solutions in metabolic and liver related diseases, today announced its annual financial results for the full year ended December 31, 2019. A summary of the consolidated financial statements is included below.

Pascal Prigent, CEO of GENFIT, commented: *"2019 has been a year of significant progress for GENFIT and, despite the current challenges due to the COVID-19 pandemic, 2020 is starting strong with a critical milestone coming up shortly.*

We are targeting the end of May to communicate the interim results of RESOLVE-IT, our Phase 3 clinical trial in patients with non-alcoholic steatohepatitis (NASH). We locked the study database in February and are now adjusting the study protocol and statistical analysis plan following recent receipt of FDA insights. We are working with our CRO (Clinical Research Organization) partner to better understand the time needed to incorporate these changes, conduct the analyses, and execute thorough standard quality checks on both side – a process that could be impacted by the fast-evolving COVID-19 pandemic. We are eagerly anticipating these results and are hopeful that they will support that elafibranor is safe and efficacious for the treatment of NASH, a disease that is affecting millions of patients globally, who are currently without any approved treatments.

In 2019, GENFIT also presented positive results from our Phase 2 trial in patients with primary biliary cholangitis (PBC) at major international congresses, showing that elafibranor was significantly better than placebo for both primary and composite endpoints of the study. Elafibranor was awarded “breakthrough therapy” and “orphan drug” designations from the FDA and EMA/FDA, respectively. PBC is a disease where there is still significant unmet medical need, and thus we are committed to the development of elafibranor for this indication. GENFIT also furthered the development of NIS4™, our non-invasive diagnostic tool for use in identifying NASH with fibrosis patients who are at risk for progression and who may benefit from treatment. This past year, NIS4™ became available for use in clinical research through our partner Labcorp-Covance and has been selected by several sponsors to assist with patient identification and recruitment for NASH clinical trials.

Beyond clinical development, 2019 was a year of important commercial activity. GENFIT signed two major deals: one with LabCorp-Covance for the development of NIS4™, and secondly with Terns Pharmaceuticals for both the licensing rights of elafibranor in Greater China and an ambitious R&D partnership. We also continued to strengthen

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our commercial team, through the hiring of new marketing talents and by partnering with leading consultancies. Together, we executed several market research and payer research studies providing valuable insight on needs and expectations of patients, healthcare professionals and payers.

Earlier in the year, we solidified our foothold in the U.S. with a successful global offering and Nasdaq initial public offering (IPO) raising gross proceeds of \$155MM. Our balance sheet was further bolstered with a \$35MM upfront payment from Terns Pharmaceuticals and we finished 2019 with a cash position of €277MM. In September, I had the pleasure of stepping into a new role as CEO with co-founder Jean-François Mouney choosing to transition to full-time leadership as Chairman of the Board, and GENFIT expanded our Executive Committee with the recruitment of a new CMO and the promotion of our Head of Diagnostic business unit. Combined with the relocation of our COO, Dean Hum, to our Cambridge, Massachusetts office, roughly half of our leadership team is now based in the U.S.

GENFIT, similar to many biotechnology companies, is affected by the COVID-19 pandemic. The RESOLVE-IT extension phase remains on-going with a few adjustments to protect our patients but, as recently communicated, the remainder of our clinical programs have been put on hold. It is still too early to accurately assess the impact these operational delays will have on our regulatory timelines for NASH, but at this stage, we estimate the timelines to shift by one to two quarters and expect to file the NDA for elafibranor in NASH in 1H21.”

Financial results

Key figures (consolidated) *

(€ thousands, except earnings per share data)

	Dec 31, 2018	Dec 31, 2019
Revenues and other incomes	7 494	40 961
R&D expenditure	(67 024)	(66 170)
General and administrative expenses	(9 076)	(17 265)
Commercial and marketing expenses	(717)	(13 708)
Other operating expenses	(162)	(1 649)
Operating loss	(69 484)	(57 832)
Financial income	728	5 221
Financial expenses	(11 118)	(13 110)
Financial loss	(10 391)	(7 889)
Net loss before tax	(79 875)	(65 721)
Income tax benefit	354	576
Net loss	(79 521)	(65 144)
Basic and diluted loss per share (€)	(2.55)	(1.76)
Cash and cash equivalents	207 240	276 748

* Financial statements are not audited. The audit procedures by the Statutory Auditors are underway. The Group adopted IFRS 16 Leases for the first time on January 1, 2019

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Revenues and other incomes

- The main contributor to our revenue stream was the \$35MM upfront payment received from Terns Pharmaceuticals for the licensing rights of elafibranor in NASH and PBC in Greater China.

Operating results and expenses

- R&D expenditures were stable and aligned with our sustained effort to progress both clinical trials and R&D activities in the diagnostic field.
- The main driver behind the increased level of expenditures is the ambitious market access, commercial and marketing plan designed to support our Launch Excellence program which is currently driven by an expanding team of internal experts and external consultants.

Cash position

- Cash position of €277MM, increased versus last year, thanks to the global financing and U.S. IPO on Nasdaq in March 2019, and the upfront payment received by Terns Pharmaceuticals in July 2019.

2020 Outlook

Clinical and regulatory update

- The announcement of the Phase 3 RESOLVE-IT interim results is now expected by the end of May. We will disclose topline results on the primary efficacy endpoint (the resolution of NASH without worsening of fibrosis), the key secondary endpoints (the improvement of fibrosis, and the recently elevated metabolic parameters) and safety. We anticipate presenting these data at one of the major hepatology congresses in the second part of the year pending confirmation of dates.
- All other clinical trials have been paused or postponed due to the COVID-19 pandemic, but will resume as soon as the situation allows clinical centers to ensure safety for patients and healthcare providers. All supporting activities pertaining to continuation of ongoing studies or the initiation of new studies will continue in order to minimize potential delays when the pandemic crisis subsides. As the situation evolves, further guidance will be provided on the following programs currently on-hold:
 - o Phase 3 clinical trial evaluating elafibranor in PBC;
 - o Phase 2 clinical trials evaluating potential synergies between elafibranor and antidiabetic drugs from the GLP-1 agonist class, and from the SGLT2 inhibitor class;
 - o Phase 2 clinical trial evaluating elafibranor in pediatric patients with NASH;
 - o Phase 2 clinical trial evaluating elafibranor's efficacy on liver fat composition in patients with NAFLD, a known precursor for NASH;
 - o Phase 1 clinical trials required for the NASH NDA dossier, which include pharmacokinetic, food effect and bioequivalence studies;
 - o Phase 2 clinical trial evaluating NTZ in fibrosis.
- NIS4™ development will continue, aiming for FDA submission of the IVD (*In Vitro Diagnostic*) in 1H21.

Commercial update

- Assuming positive Phase 3 RESOLVE-IT interim results for elafibranor in NASH, GENFIT will:
 - o prepare the full dossier for the NDA submission now targeted in 1H21;
 - o consolidate its global market access and commercial strategy for elafibranor in NASH, capitalizing on the valuable insights gained from the extensive market research effort initiated in 2019, to shape the market and optimize potential sales uptake at the time of launch;

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- NIS4™ technology will continue to be deployed in the clinical research field through our commercial partner LabCorp-Covance, and expansion plans are underway, with a goal to commercialize this technology as a Laboratory Developed Test (LDT) beyond the clinical research environment. This 2H20 expected roll-out is considered as an essential step aimed at developing the recognition of the NIS4™ technology, within the KOL community, and ahead of the IVD FDA submission.

Financial update

- GENFIT does not provide guidance on expected cash burn and anticipated cash runway. Expenditures in 2020 will strongly depend on the nature of the topline results from the RESOLVE-IT Phase 3 clinical trial, which remain unknown as of today.

2019 Key Highlights

Clinical and regulatory milestones

- **Investigation of elafibranor in NASH**

- In May and November, GENFIT announced Data and Safety Monitoring Board (DSMB) recommendations for the continuation of the Phase 3 RESOLVE-IT study of elafibranor in NASH without modification following their review at 36- and 42-months, respectively;
- In May, GENFIT announced the initiation of a combination therapy clinical program in NASH to investigate elafibranor as a backbone in combination with a GLP-1 agonist and in combination with an SGLT-2 inhibitor. The metabolic mechanisms of elafibranor (a PPAR alpha/delta agonist) and the mechanisms of other therapies may provide additive or synergistic effects by addressing the underlying drivers of NASH progression;
- In early June, GENFIT launched a Phase 2 trial to evaluate elafibranor's activity on hepatic lipid composition for NAFLD. The study is designed to explore how elafibranor's pluripotent PPAR alpha and delta mechanism of action, could be beneficial by improving quantity and quality of fat in the liver, specifically targeting the more harmful, lipotoxic fat subtypes that buildup in NAFLD and drive progression to NASH.

- **Investigation of elafibranor in PBC**

- In April, at EASL ILC, GENFIT presented detailed data from the Phase 2 clinical trial of elafibranor in PBC, showing a reduction in alkaline phosphatase (ALP) of 52% (80mg) and 44% (120mg) when compared to placebo ($p < 0.001$). In addition, elafibranor demonstrated a statistically significant response rate of 67% (80mg, $p = 0.002$) and 79% (120mg, $p < 0.001$) versus 6.7% (placebo) on the composite endpoint previously used for regulatory approval of the current second line treatment. Elafibranor was associated with significant improvements in cholestatic markers, reduction on immune/inflammation markers, decrease in bile acid precursors, and improvement in metabolic markers. Additional data also suggested potential improvement in pruritus, which will be further evaluated in a Phase 3 study. The Phase 2 efficacy and safety data are supportive of longer-term, larger scale studies in patients with PBC;
- In April, the FDA granted elafibranor "Breakthrough Therapy" designation for the treatment of PBC in adults with inadequate response to UDCA, and in July the FDA and EMA granted elafibranor "Orphan Drug" designation for PBC.

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- **NIS4™**

- At AASLD, in November 2019, GENFIT presented new data suggesting that NIS4™ was able to outperform other non-invasive diagnostics in identifying NASH with fibrosis in people with type 2 diabetes, a known risk-factor for NASH.

Commercial milestones

- In January 2019, GENFIT announced a licensing agreement with LabCorp-Covance to expand access to its NIS4™ technology for the identification and monitoring of patients with NASH and fibrosis for the clinical research market. NIS4™, a non-invasive blood-based tool, is now utilized by LabCorp-Covance in their clinical research setting for the identification of patients with NASH and fibrosis (NAS \geq 4, F \geq 2), to optimize patient enrollment in clinical trials;
- In late June, GENFIT announced a \$228MM strategic partnership deal with Terns Pharmaceuticals for the development and commercialization of elafibranor for the treatment of NASH and PBC in Greater China. GENFIT received a \$35MM upfront payment from Terns, and is eligible to receive up to \$193MM in potential clinical, regulatory, and commercial milestone payments, as well as mid-teen percentage royalties on sales in the territory.

Governance and organizational evolution

- **Leadership**

- In September, GENFIT announced the appointment of Pascal Prigent as CEO, and Jean-François Mouney's decision to transition to full-time Chairman of the Board. The team also added Dr. Carol L. Addy as Chief Medical Officer, based in Cambridge, Massachusetts;
- Later in September, GENFIT announced the appointments of Dr. Dean Hum as President of GENFIT Corp. and Dr. Suneil Hosmane as Head of Global Diagnostics, both based at GENFIT's U.S. headquarters in Cambridge, Massachusetts.

- **Corporate headcount growth**

- In 2019, GENFIT's global headcount increased from 148 to 194 employees, through new department creation and expansion of existing teams: market access, commercial, medical affairs, pharmacovigilance, etc.

Conference Call on April 9, 2020 at 8:00 AM EDT / 14:00 CEST

- GENFIT will host a Full-Year 2019 Financial Results and Corporate Update conference call on Thursday, April 9, 2020 at 8:00 AM EDT/14:00 CEST. The conference call will be accessible on the investor page of our website, under the events section at <https://ir.genfit.com/> or by calling 877-407-9167 (toll-free U.S. and Canada), 201-493-6754 (international) or 0 800 912 848 (France) five minutes prior to the start time (no passcode needed). A replay will be available shortly after the call.

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APPENDICES

Consolidated Statement of Financial Position*

ASSETS (in € thousands)	As of	
	2018/12/31	2019/12/31
Current assets		
Cash and cash equivalents	207 240	276 748
Current trade and other receivables	8 794	12 033
Other current assets	2 078	1 968
Inventories	4	4
Total - Current assets	218 116	290 753
Non-current assets		
Intangible assets	796	920
Property, plant and equipment	7 764	16 453
Non-current trade and others receivables	1 489	0
Other non-current financial assets	1 313	1 727
Deferred tax assets	0	0
Total - Non-current assets	11 362	19 099
Total - Assets	229 478	309 853

SHAREHOLDERS' EQUITY AND LIABILITIES (in € thousands)	As of	
	2018/12/31	2019/12/31
Current liabilities		
Current convertible loans	1 312	1 312
Other current loans and borrowings	1 848	3 065
Current trade and other payables	35 974	36 917
Current deferred income and revenue	1	139
Current provisions	112	2 061
Total - Current liabilities	39 248	43 495
Non-current liabilities		
Non-current convertible loans	159 176	164 142
Other non-current loans and borrowings	7 255	15 100
Non-current trade and other payables	(0)	450
Non-current employee benefits	1 085	1 408
Deferred tax liabilities	1 773	1 193
Total - Non-current liabilities	169 291	182 293
Shareholders' equity		
Share capital	7 796	9 715
Share premium	251 554	377 821
Accumulated deficit	(158 897)	(238 340)
Currency translation adjustment	6	14

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Net loss	(79 521)	(65 144)
Total shareholders' equity - Group share	20 939	84 065
Non-controlling interests	0	0
Total - Shareholders' equity	20 939	84 065
Total - Shareholders' equity & liabilities	229 478	309 853

* Financial statements are not audited. The audit procedures by the Statutory Auditors are underway The Group adopted IFRS 16 Leases for the first time on January 1, 2019

Statement of Operations*

(in € thousands, except earnings per share data)	Year ended	
	2018/12/31	2019/12/31
Revenues and other income		
Revenue	69	30 839
Other income	7 425	10 122
Revenues and other income	7 494	40 961
Operating expenses and other operating income (expenses)		
Research and development expenses	(67 024)	(66 170)
General and administrative expenses	(9 076)	(17 265)
Marketing and market access expenses	(717)	(13 708)
Other operating income (expenses)	(162)	(1 649)
Operating loss	(69 484)	(57 832)
Financial income	728	5 221
Financial expenses	(11 118)	(13 110)
Financial loss	(10 391)	(7 889)
Net loss before tax	(79 875)	(65 721)
Income tax benefit	354	576
Net loss	(79 521)	(65 144)

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Statement of Cash Flows*

(in € thousands)	Year ended 31/12/2018	Year ended 31/12/2019
Cash flows from operating activities		
+ Net loss	(79 521)	(65 144)
+ Non-controlling interests	0	0
Reconciliation of net loss to net cash used in operating activities		
Adjustments for:		
+ Amortization	1 819	3 263
+ Depreciation and impairment charges	(208)	2 143
+ Expenses related to share-based compensation	787	1 657
- Gain on disposal of property, plant and equipment	(2)	(19)
+ Net finance expenses	10 971	11 437
+ Income tax expense	(354)	(576)
+ Other non-cash items	0	(83)
Operating cash flows before change in working capital	(66 507)	(47 324)
Change in:		
Decrease / (increase) in inventories	(0)	0
Increase in trade receivables and other assets	(724)	(1 640)
Increase in trade payables and other liabilities	11 056	1 284
Change in working capital	10 332	(356)
Income tax paid	93	0
Net cash flows used in operating activities	(56 081)	(47 680)
Cash flows from investment activities		
- Acquisition of property, plant and equipment	(2 938)	(2 030)
+ Proceeds from disposal of property, plant and equipment	3	2 517
- Acquisition of financial instruments	(1 050)	(160)
+ Proceeds from sale of financial instruments	0	0
- Acquisition of subsidiary, net of cash acquired	0	0
Net cash flows provided by / (used in) investment activities	(3 986)	327
Cash flows from financing activities		
+ Proceeds from issue of share capital (net)	0	126 486
+ Proceeds from subscription / exercise of share warrants	37	43
+ Proceeds from new loans and borrowings net of issue costs	1 800	0
- Repayments of loans and borrowings	(2 000)	(1 884)
- Financial interests paid (including finance lease)	(6 351)	(7 785)
Net cash flows provided by / (used in) financing activities	(6 514)	116 860
Increase / (decrease) in cash and cash equivalents	(66 580)	69 508
Cash and cash equivalents at the beginning of the period	273 820	207 240

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Cash and cash equivalents at the end of the period

207 240

276 748

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ABOUT GENFIT

GENFIT is a late-stage biopharmaceutical company dedicated to the discovery and development of innovative therapeutic and diagnostic solutions in metabolic and liver related diseases where there are considerable unmet medical needs, corresponding to a lack of approved treatments. GENFIT is a leader in the field of nuclear receptor-based drug discovery, with a rich history and strong scientific heritage spanning more than two decades. Its most advanced drug candidate, elafibranor, is currently being evaluated in a pivotal Phase 3 clinical trial ("RESOLVE-IT") as a potential treatment for NASH and GENFIT plans to initiate a Phase 3 clinical trial of elafibranor in patients with PBC. As part of GENFIT's comprehensive approach to clinical management of patients with NASH, the company is also developing a new, non-invasive blood-based diagnostic test, NIS4™, which could enable easier identification of patients with NASH. With facilities in Lille and Paris, France, and Cambridge, MA, USA, the Company has approximately 200 employees. GENFIT is a publicly traded company listed on the Nasdaq Global Select Market and on compartment B of Euronext's regulated market in Paris (Nasdaq and Euronext: GNFT). www.genfit.com

FORWARD LOOKING STATEMENT/DISCLAIMER

This press release contains certain forward-looking statements, including those within the meaning of the Private Securities Litigation Reform Act of 1995, with respect to GENFIT, including timing of publication of the top-line interim results of our Phase 3 RESOLVE-IT clinical trial, timing of our NDA submission regarding elafibranor in NASH, the impacts of the COVID-19 pandemic on our business, timing of clinical and regulatory milestones and our financial perspective, regulatory and development timelines for our NIS4™ technology and its availability as an LDT beyond the clinical research environment, and our ability to continue supporting activities and to minimize potential delays once the COVID-19 pandemic subsides. The use of certain words, including "believe," "potential," "expect" and "will", "provisional" and similar expressions, is intended to identify forward-looking statements. These forward-looking statements are based on assumptions and estimates by our management, which, although believed to be reasonable, 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"), including those listed in Section 4 "Main Risks and Uncertainties" of the Company's 2018 Registration Document filed with the AMF on February 27, 2019 under n° D.19-0078, which is available on GENFIT's website (www.genfit.com) and on the website of the AMF (www.amf-france.org) and public filings and reports filed with the U.S. Securities and Exchange Commission ("SEC"), including the Company's final prospectus dated March 26, 2019, and subsequent filings and reports filed with the AMF or SEC, or otherwise made public, by the Company. In addition, even if the Company's results, performance, financial condition and liquidity, and the development of the industry in which it operates are consistent with such forward-looking statements, they may not be

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predictive of results or developments in future periods. These forward-looking statements speak only as of the date of publication of this document. 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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