



## PRESS RELEASE

### **ANNUAL RESULTS 2015: END-OF-YEAR CASH POSITION OF €60M AND MAJOR PROGRESS IN THE DIAGNOSIS AND THE TREATMENT OF NASH**

- › **Cash horizon to early 2017**
- › **Phase IIb clinical results for Elafibranor in NASH led to the launch of a Phase III study in the same therapeutic indication**
- › **Discovery of a diagnostic tool that could replace the liver biopsy for the identification of NASH patients to be treated**

**Lille (France), Cambridge (Massachusetts, United States), February 4<sup>th</sup>, 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 announces its financial results for 2015. The consolidated financial statements are attached to this press release.

**Jean-François Mouney, Chairman & CEO of GENFIT**, commented: *“2015 was an important year for GENFIT, with major progress in both the diagnosis and the treatment of NASH.*

*Elafibranor, our leading drug candidate, obtained satisfactory results in the Phase IIb study GOLDEN 505, both in terms of efficacy and safety.*

*Moreover, our teams have developed a diagnostic tool based on algorithms including a new type of biomarker that enables the identification of NASH patients that should be treated with Elafibranor, without the need for an invasive liver biopsy. This tool, if validated during the further clinical development of Elafibranor, would substantially increase the prescription potential of anti-NASH drugs.*

*Finally, as the result of a joint initiative of major regulatory agencies and key scientific and medical opinion leaders in NASH, significant regulatory progress has been made in 2015. This progress clarifies market access for NASH drug candidates in general, and Elafibranor in particular.*

*For all these reasons, we decided to launch the Phase III of Elafibranor in NASH at the end of 2015. 2016 will therefore be a key year for its further development or co-development in this therapeutic indication.”*



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### Financial highlights :

The financial results for 2015 are marked by a controlled cash situation, in the absence of fund raising during the financial year. The year-end cash position is thus €60.1 million. This translates into a cash horizon to the beginning of 2017 in a context of increased R&D expenses related to the launch of the Phase III clinical trial of Elafibranor in NASH.

The key elements of the 2015 financial results are as follows:

- Cash, cash equivalents and financial instruments amounting to €60.1 million as of December 31, 2015 (€76.3 million as of December 31, 2014);
  - At the same date, the financial debt amounted to €5.7 million (€6.6 million as of December 31, 2014)
- Revenue and other income amounted to €4.4 million (€6.8 million as of December 31, 2014), primarily from industrial revenue and research tax credit;
  - Industrial revenue amounted to €0.53 million in 2015 (€1.6 million in 2014), and was mainly due to revenue generated by the prolongation until May 2015 of the co-research alliance with Sanofi (the revenue generated in 2014 included a milestone payment of €1 million)
- Operating expenses amounted to €22 million (€24 million in 2014), of which 74% was devoted to research and development;
- As a result of these changes in revenues and expenses, the operating loss amounted to €17.1 million (€17 million in 2014).



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The following table summarizes the IFRS consolidated financial statements for the 2015 financial year, in comparison to the 2014 financial year:

(in € thousands, except earnings per share data)	Year ended December 31,	
	2014	2015
<b>Revenues and other income</b>		
Revenue	1 614	527
Other income	5 161	3 831
<b>Total - Revenues and other income</b>	<b>6 776</b>	<b>4 358</b>
<b>Operating expenses and other operating income (expenses)</b>		
Research & development expenses	(18 111)	(16 360)
General & administrative expenses	(5 879)	(5 630)
Other operating income	10	2
Other operating expenses	(55)	(47)
<b>Operating loss</b>	<b>(17 259)</b>	<b>(17 676)</b>
Financial revenue	492	642
Financial expenses	(259)	(100)
<b>Financial income</b>	<b>234</b>	<b>542</b>
Income tax	(0)	(0)
<b>Net loss</b>	<b>(17 025)</b>	<b>(17 135)</b>

The IFRS consolidated annual financial statements as of December 31, 2015, as well as the management discussion of these results, are presented in the appendix at the end of this document.



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### APPENDICES

#### GENFIT

<p><b>Consolidated annual financial statements</b> <b>As of December 31, 2015</b></p>
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The consolidated statement of comprehensive income, consolidated statement of financial position and consolidated statement of cash flow of the Group are prepared in accordance with International Financial Reporting Standards.

The audit procedures on the consolidated financial statements have been performed. The consolidated financial statements were approved by the Executive Board on February 1, 2016. These statements were reviewed by the Supervisory Board on February 1, 2016 and will be submitted for approval to the Shareholders' General Meeting on June 21, 2016.

The Annual Financial Report of GENFIT will be made available on the website of the Company in February 2016.



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### Consolidated Statement of Financial Position

ASSETS (in € thousands)	Year ended December 31,	
	2014	2015
<b>Non-current assets</b>		
Goodwill	75	0
Intangible assets	86	563
Property, plant & equipment	1 333	1 324
Non current trade & others receivables	0	7
Other non-current financial assets	1 060	612
<b>Total - Non-current assets</b>	<b>2 553</b>	<b>2 505</b>
<b>Current assets</b>		
Inventories	248	28
Current trade & others receivables	6 702	5 998
Other current financial assets	4 025	31
Other current assets	833	585
Cash & cash equivalents	72 005	60 111
<b>Total - Current assets</b>	<b>83 813</b>	<b>66 753</b>
<b>Total - Assets</b>	<b>86 366</b>	<b>69 258</b>
<b>EQUITY &amp; LIABILITIES</b>		
(in € thousands)	Year ended December 31,	
	2014	2015
<b>Shareholders' equity</b>		
Share capital	5 989	5 990
Share premiums	115 757	118 038
Retained earnings	(34 278)	(51 492)
Currency translation adjustment	(15)	15
Net loss	(17 025)	(17 135)
<b>Total shareholders' equity - Group share</b>	<b>70 429</b>	<b>55 416</b>
Non-controlling interests	0	0
<b>Total - Shareholders' equity</b>	<b>70 429</b>	<b>55 416</b>
<b>Non-current liabilities</b>		
Non-current loans & borrowings	4 931	4 482
Non-current deferred income and revenue	1	5
Non-current employee benefits	614	743
<b>Total - Non-current liabilities</b>	<b>5 546</b>	<b>5 229</b>
<b>Current liabilities</b>		
Current loans & borrowings	1 687	1 223
Current trade & other payables	8 438	7 292
Current deferred income and revenue	260	29
Current provisions	6	69
<b>Total - Current liabilities</b>	<b>10 391</b>	<b>8 613</b>
<b>Total - Equity &amp; liabilities</b>	<b>86 366</b>	<b>69 258</b>



## PRESS RELEASE

### Consolidated Statement of Comprehensive Income

(in € thousands, except earnings per share data)	Year ended December 31,	
	2014	2015
<b>Revenues and other income</b>		
Revenue	1 614	527
Other income	5 161	3 831
<b>Total - Revenues and other income</b>	<b>6 776</b>	<b>4 358</b>
<b>Operating expenses and other operating income (expenses)</b>		
Research & development expenses	(18 111)	(16 360)
General & administrative expenses	(5 879)	(5 630)
Other operating income	10	2
Other operating expenses	(55)	(47)
<b>Operating loss</b>	<b>(17 259)</b>	<b>(17 676)</b>
Financial revenue	492	642
Financial expenses	(259)	(100)
<b>Financial income</b>	<b>234</b>	<b>542</b>
Income tax	(0)	(0)
<b>Net loss</b>	<b>(17 025)</b>	<b>(17 135)</b>
Attributable to owners of the Company	(17 025)	(17 135)
<b>Basic / diluted loss per share attributable to shareholders of GENFIT</b>		
Basic earnings per share (€/share)	(0.76)	(0.71)



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### Consolidated Statement of Cash Flow

(in € thousands)	Year ended December 31,	
	2014	2015
<b>Cash flows from operating activities</b>		
+ Net loss	(17 025)	(17 135)
<b>Reconciliation of net loss and of the cash used for operating activities</b>		
Adjustments for:		
+ Amortization & depreciation	292	327
- Net gain / (loss) on disposals	(10)	3
- Net finance expenses / (revenue)	94	(27)
- Expenses related to share-based compensation	1 051	2 012
+ Provisions	53	237
- Income tax expense	0	0
+ Other non-cash items	(43)	10
Operating cash flows before change in working capital	(15 588)	(14 572)
<b>Change in:</b>		
Decrease (+) / increase (-) in inventories	(81)	219
Decrease (+) / increase (-) in trade receivables & other assets	(1 315)	946
Decrease (-) / increase (+) in trade payables & other liabilities	1 538	(1 462)
Change in working capital	142	(297)
Income tax paid	0	0
<b>Net cash flows provided by (used in) operating activities</b>	<b>(15 445)</b>	<b>(14 870)</b>
<b>Cash flows from investment activities</b>		
- Acquisition of property, plant & equipment	(721)	(790)
+ Proceeds from disposal of property, plant & equipment	15	2
- Acquisition of financial instruments	(4 300)	(16)
+ Proceeds from sale of financial instruments	0	4 300
- Acquisition of subsidiary, net of cash acquired	0	0
<b>Net cash flows provided by (used in) investing activities</b>	<b>(5 006)</b>	<b>3 496</b>
<b>Cash flows from financing activities</b>		
+ Proceeds from issue of share capital (net)	72 296	2
+ Proceeds from subscription / exercise of share warrants	86	267
+ Proceeds from new loans & borrowings	857	807
- Repayments of loans & borrowings	(1 606)	(1 609)
- Financial interests paid (including finance lease)	(98)	13
<b>Net cash flows provided by (used in) financing activities</b>	<b>71 535</b>	<b>(520)</b>
<b>Increase / (decrease) in cash &amp; cash equivalents</b>	<b>51 083</b>	<b>(11 894)</b>
<b>Cash &amp; cash equivalents at the beginning of the period</b>	<b>20 922</b>	<b>72 005</b>
Financial assets reclassified as short-term deposits	0	0
<b>Cash &amp; cash equivalents at the end of the period</b>	<b>72 005</b>	<b>60 111</b>



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### Management discussion on annual results for 2015

#### Revenue and other income

Revenue and income of the Company result from industrial revenue and other operating income including mostly the research tax credit. Our revenue and other income were respectively €4.4 million and €6.8 million for the fiscal years ended December 31, 2015 and 2014, from the following sources:

Revenue and other income (in € thousands)	Year ended December 31,	
	2014	2015
Revenues	1 614	527
Other income	5 161	3 831
<b>TOTAL</b>	<b>6 776</b>	<b>4 358</b>

#### Industrial Revenues

Industrial revenues totaled €0.5 million in 2015 compared with €1.6 million in 2014. These revenues essentially result from the prolongation of the co-research alliance with Sanofi, until May 2015.

The decrease in revenue in 2015 reflects the end of the research sharing phase between the teams of Sanofi and the Company in May 2015; moreover, the revenue generated in the course of the fiscal year 2014 included a milestone payment of €1 million made by Sanofi for reaching a scientific milestone contractually agreed upon in the last three-year co-research contract.

#### Other income

Other income (in € thousands)	Year ended December 31,	
	2014	2015
Government grants	94	12
Research tax credit	4 973	3 705
Other operating income	94	114
<b>TOTAL</b>	<b>5 161</b>	<b>3 831</b>

The amount of the research tax credit is based on 30% of the eligible expenses of the fiscal year. With the decrease of the eligible expenditure, the research tax credit amounts to €3.7 million compared with €5 million in 2014.

When research tax credit is not deductible from taxes payable by the Company, it is usually reimbursed by the French government during the fourth fiscal year following the period for which it was booked in the income statement. Since 2010, companies classified as small and medium sized ("SMEs") according to the European Union criteria, including GENFIT SA, are eligible for an early reimbursement of the research tax credit.





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### Analysis of operating expenses by function and nature

The table below analyzes the operating expenses by function for the fiscal years ended December 31, 2014 and 2015:

Operating expenses and other operating income (expenses)	December 31, 2014	Of which:					Gain / (loss) on disposal of property, plant & equipment
		Raw materials & consumables used	Contracted research & development activities conducted by third parties	Employee expenses	Other operating expenses	Depreciation, amortization & impairment charges	
(in € thousands)							
Research & development expenses	(18 111)	(1 332)	(9 020)	(5 347)	(2 168)	(245)	0
General & administrative expenses	(5 879)	(73)	0	(4 018)	(1 815)	26	0
Other operating income	10	0	0	0	0	0	10
Other operating expenses	(55)	0	0	0	(55)	0	0
<b>TOTAL</b>	<b>(24 034)</b>	<b>(1 404)</b>	<b>(9 020)</b>	<b>(9 365)</b>	<b>(4 037)</b>	<b>(219)</b>	<b>10</b>

Operating expenses and other operating income (expenses)	December 31, 2015	Of which:					Gain / (loss) on disposal of property, plant & equipment
		Raw materials & consumables used	Contracted research & development activities conducted by third parties	Employee expenses	Other operating expenses	Depreciation, amortization & impairment charges	
(in € thousands)							
Research & development expenses	(16 360)	(1 863)	(5 389)	(6 289)	(2 356)	(459)	(3)
General & administrative expenses	(5 630)	(68)	(0)	(2 840)	(2 675)	(46)	0
Other operating income	2	0	0	0	1	0	1
Other operating expenses	(47)	0	0	0	(43)	(2)	(2)
<b>TOTAL</b>	<b>(22 034)</b>	<b>(1 930)</b>	<b>(5 390)</b>	<b>(9 130)</b>	<b>(5 074)</b>	<b>(508)</b>	<b>(3)</b>

Operating expenses of the fiscal year totaled €22 million compared with €24 million for the previous fiscal year, representing a decrease of 8.3%. They consist in particular of:

- research and development expenses, which include the costs of staff assigned to research (€6.3 million in 2015), the costs of consumables and operational outsourcing (especially clinical and pharmaceutical), and expenses related to intellectual property. These research and development expenses amounted to €16.4 million in 2015 compared with €18.1 million in 2014, respectively 74% and 75% of the operating expenses.
- general and administrative expenses, which include the costs of staff not assigned to research (€2.8 million), and the administrative and commercial costs. These general and administrative expenses amounted to €5 million in 2015 compared with €5.9 million in 2014, respectively 26% and 24% of operating expenses.



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### Raw materials and consumables

Raw materials and consumables totaled €1.9 million compared with €1.4 million for the previous fiscal year, representing an increase of 37%. This evolution is essentially linked to the increase of laboratory staff, and reflects in particular the efforts made by the Group in its research and development program called TGFTX1 and in its program of development of NASH biomarker candidates (BMGFT03).

### Contracted research and development activities conducted by third parties

Costs included under this heading totaled €5.4 million compared with €9 million for the previous fiscal year, representing a decrease of 40.2%, essentially linked to the completion of the Phase IIb clinical trial of Elafibranor in NASH.

### Employee expenses

Employee expenses (in € thousands)	Year ended December 31,	
	2014	2015
Wages and salaries	(5 775)	(4 906)
Social security costs	(2 562)	(2 154)
Pension costs	20	(57)
Individual training entitlement	3	0
Share-based compensation	(1 051)	(2 012)
<b>TOTAL</b>	<b>(9 365)</b>	<b>(9 130)</b>

Employee expenses amounted to €9.1 million compared with €9.4 million for the previous fiscal year, representing a decrease of 2.5%.

Among these expenses and notwithstanding the increase in staff in 2015 (96 employees on 31 December 2015 compared to 81 on 31 December 2014), the amount of wages and social security costs decreased.

On the other hand, the amount recognized as share-based compensation without impact on the cash flow increased from €1.1 million in 2014 to €2 million in 2015.

### Other operating expenses

Other operating expenses amounted to €5.1 million compared with €4 million for the previous fiscal year, representing an increase of 28%. This evolution is essentially linked to the strengthening of the activity and presence of the Group in the United States.

### **Financial results**

The financial result is €0.5 million compared with €0.2 million for the previous fiscal year.

The Company's cash investment policy favors the absence of risk on capital and, wherever possible, guaranteed minimum performance.



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### **Income tax**

Because of its accumulated reportable losses, the Company has not recorded income tax expense. Furthermore, no deferred tax asset has been recognized during the fiscal year as there is a minimal likelihood of recovery.

In the consolidated financial statement, in accordance with IFRS, the research tax credit is classified as "other income" and not in the line income tax.

### **Net income/loss per share**

The net loss per share amounted respectively to €0.76 and €0.72 for the fiscal years ended 31 December 2014 and 2015.

### **Statement of financial position items**

Since its creation, the Group has been financed mainly by the revenues from its co-research alliances, by issuing new securities, by the research tax credit and by repayable advances and grants received from different public bodies.

Financial debt amounted to €5.7 million as of December 31, 2015.

Cash, cash equivalents and financial instruments amounted to €60.1 million as of December 31, 2015, compared with €76.3 million as of December 31, 2014.

### **Events after the reporting period**

No significant event has occurred after the reporting period.

### **Annual Financial Report**

The Group will make available its Annual Financial Report on its website ([www.genfit.com](http://www.genfit.com)) in February 2016.



## PRESS RELEASE

### 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 implements mutually beneficial approaches that combine novel treatments and biomarkers; its research programs have resulted in the creation of a rich and diversified pipeline of drug candidates, including GENFIT's lead proprietary compound, Elafibranor (GFT505), that has completed a positive Phase 2b study in NASH and is currently launching a Phase 3 study. With facilities in Lille, France, and Cambridge, MA (USA), the Company has approximately 100 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)

### 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 anticipated. For a discussion of risks and uncertainties which could cause the Company's actual results, financial condition, performance or achievements to differ from those contained in the forward-looking statements, please refer to the Risk Factors ("Facteurs de Risque") section of the Listing Prospectus upon the admission of Company's shares for trading on the regulated market Euronext of Euronext Paris filed with the AMF, which is available on the AMF website ([www.amf-france.org](http://www.amf-france.org)) or on GENFIT's website ([www.genfit.com](http://www.genfit.com)).

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. Items in this press release may contain forward-looking statements involving risks and uncertainties. The Company's actual results could differ substantially from those anticipated in these statements owing to various risk factors which are described in the Company's prospectus. 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.

### CONTACT

**GENFIT** | Jean-François Mouney – Chairman & CEO | Ph. +333 2016 4000

**MILESTONES – Press Relations** | Bruno Arabian | Ph. +331 8362 3484 / +336 8788 4726 – [barabian@milestones.fr](mailto:barabian@milestones.fr)

**GENFIT** | 885 Avenue Eugène Avinée, 59120 Loos - FRANCE | +333 2016 4000 | [www.genfit.com](http://www.genfit.com)