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GENFIT: Reports Full-Year 2018 Financial Results: cash position of €207.2m as of 12.31.2018

GENFIT achieved significant development milestones in 2018:

- Completed enrollment of interim analysis cohort for phase 3 RESOLVE-IT trial in NASH
- Announced positive results in phase 2 trial of elafibranor in PBC
- Entered into licensing agreement with LabCorp® for NASH diagnostic
- Launched a U.S. phase 2 investigator-initiated trial of nitazoxanide in patients with NASH-induced fibrosis

Cash position of €207.2 million as of December 31, 2018, compared to €273.8 million as of December 31, 2017

Lille (France), Cambridge (Massachusetts, United States), February 4, 2019 – GENFIT (Euronext: GNFT - ISIN: FR0004163111), a late-stage biopharmaceutical company dedicated to the discovery and development of innovative therapeutic and diagnostic solutions in metabolic and liver related diseases, today announces its annual financial results for 2018. A summary of the consolidated financial statements is included below.

Jean-François Mouney, Chairman & CEO of GENFIT, commented: *"The lead programs in our clinical and diagnostic pipeline, in particular the later-stage ones in NASH and PBC, have moved forward considerably and met our corporate 2018 milestones. We completed enrollment for the interim analysis cohort of our phase 3 RESOLVE-IT trial of elafibranor in NASH, achieved positive results in the phase 2 trial of elafibranor in PBC and accomplished significant milestones in the regulatory and commercial development of our biomarker program, leading to the signature of a licensing agreement with LabCorp® in early January this year. Our objective with this agreement is, in particular, to expand access to NIS4, GENFIT's non-invasive in vitro diagnostic test, in order to identify NASH patients who should be considered for therapeutic intervention. Our program to reposition nitazoxanide in liver fibrosis took shape with the launch of a U.S. phase 2 trial in patients with NASH induced fibrosis. Additional pre-clinical research results completed in 2018 suggest that elafibranor is uniquely positioned as a backbone for combination therapies in NASH, including with our nitazoxanide program.*

Finally, we believe our strong cash position allows GENFIT substantial flexibility as we prepare for a potential conditional marketing authorization for elafibranor in NASH in 2020."

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Key 2018 R&D Developments

January 2018

- GENFIT announced the official launch of elafibranor in pediatric NASH, following an agreement from the U.S. Food and Drug Administration (FDA) on the Company's pediatric study plan (PSP).

April 2018

- GENFIT announced completion of the target recruitment for the interim analysis cohort of the phase 3 RESOLVE-IT trial of elafibranor in NASH.
- GENFIT also announced the positive outcome from the 24-month pre-planned safety review by the Data Safety Monitoring Board (DSMB) in the RESOLVE-IT phase 3 clinical trial with elafibranor.

June 2018

- GENFIT announced new preclinical study results suggesting that elafibranor has anti-tumor development activity in the context of NAFLD/NASH-induced hepatocellular carcinoma (HCC).

August 2018

- GENFIT announced the achievement of the full enrollment in the phase 2 trial of elafibranor in PBC ,a major milestone

October 2018

- GENFIT presented new data at the annual AASLD conference confirming:
 - the diagnostic performance of its NIS4 algorithm in identifying, in a non-invasive way, NASH patients eligible to therapeutic intervention.
 - elafibranor's potential as cornerstone drug in combination therapies for NASH; and
 - elafibranor's potential in treating hepatic cancer (HCC)

December 2018

- GENFIT announced the initiation of a phase 2 investigator-initiated clinical trial evaluating nitazoxanide) in patients with NASH-induced fibrosis.
- GENFIT also announced positive results from its phase 2 trial of elafibranor in PBC.

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- Elafibranor met the primary endpoint of the Phase 2 clinical trial, which was the change at week 12 in serum alkaline phosphatase (ALP) from baseline. Both elafibranor doses demonstrated significant decrease in mean ALP: -48% for 80 mg -41% for 120 mg with +3% increase for placebo leading to highly significant treatment effect versus placebo: -52% for 80 mg ($p<0.001$) and -44% for 120 mg ($p<0.001$).
- On the composite endpoint of the responder rate for patients achieving serum ALP $<1.67 \times$ Upper Limit of Normal (ULN), an ALP decrease $>15\%$, and total bilirubin (TB) $<ULN$, elafibranor achieved the substantially higher response rates of 67% for 80 mg and 79% for 120 mg as compared to 6.7% for placebo ($p=0.001$ and $p<0.001$, respectively).
- GENFIT provided an update in December on the positive outcome from the 30-month pre-planned safety review by the DSMB in the RESOLVE-IT phase 3 clinical trial with elafibranor.

January 2019

- GENFIT announced it had signed a licensing agreement with LabCorp® to expand access to its NIS4 test for the identification and monitoring of patients with NASH and significant fibrosis in the clinical research market. The objective of this test is to provide these actors with a non-invasive diagnostic tool to identify and monitor patients with NASH and advanced stage fibrosis.

Other Corporate Events

- On June 12, 2018, the Company, through the endowment fund it founded, *The NASH Education Program™*, organized the first International NASH Day, which garnered significant interest from the international scientific and medical communities, patients and media.

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Full-Year 2018 Financial Results (consolidated IFRS accounts) (*)

A summary of the key aspects of GENFIT's 2018 annual results are:

- Cash, cash equivalents and other current financial assets of €207.2 million at December 31, 2018 (€273.8 million at December 31, 2017) in a context of a significant increase in operating expenses relating to the progression of the R&D pipeline;
- Operating income of €7.5 million (€6.9 million at December 31, 2017) essentially from the Research Tax Credit, which amounted to €7.3 million for 2018 compared with €6.5 million in 2017;
- Operating expenses of €77.0 million (€63.6 million in 2017) of which 87% represented R&D expenses. The increase in operating expenses is due to:
 - the increase in contracted R&D expenses resulting from the progression of the R&D program pipeline, of which the majority related to expenses for the phase 3 elafibranor trial in NASH, and to a lesser extent, the phase 2 trial of elafibranor in PBC and the launch of the phase 2 trial of nitazoxanide;
 - an increase in payroll expense, resulting mainly from changes in employee profiles, salary increases, and the increase in headcount (from 125 at December 31, 2017 to 148 at December 31, 2018); and
 - an increase in other operating expenses in particular relating to intellectual property expenses and fees and expenses in the preparation for the commercialization of elafibranor in NASH.
- As a result of changes in revenues and expenses, a net loss of €79.5 million at December 31, 2018 (€55.7 million in 2017) (*).

(*) In the context of the preparation of its 2018 consolidated financial statements, the Company adjusted the financial statements previously published for the 2017 fiscal year under IFRS. These changes do not affect the cash position or the operating results, and are related to the application of IFRS to deferred taxes on the OCEANE bonds issued in October 2017. The corrections lead mainly to a decrease in the consolidated net loss of €2.9 million. More information is provided on Appendix 2.

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- Net cash flows from operations in 2018 and 2017 were €(56.1) million and €(49.9) million respectively, mainly due to the increase in the Group's R&D activities;
- Net cash flows from investment activities were €(4.0) million in 2018 compared to €(2.9) million in 2017 ; this change is mainly due to the additional amount allocated to the liquidity agreement ;
- Net cash flows from financing activities in 2018 and 2017 amounted to, €(6.5) million and €174.3 million, respectively, following the issuance in 2017 of convertible bonds (OCEANE) due October 16, 2022 in a private placement to institutional investors for a nominal amount of approximately €180 million.

(in € millions)	Year ended	
	2017/12/31 (*)	2018/12/31
Revenues and other income	6.9	7.5
Research and development expenses	(54.2)	(67.0)
General and administrative expenses	(9.4)	(9.8)
Operating loss	(56.7)	(69.5)
Net loss	(55.7)	(79.5)
Net cash flows used in operating activities	(49.9)	(56.1)
Net cash flows used in investment activities	(2.9)	(4.0)
Net cash flows provided by / (used in) financing activities	174.3	(6.5)
Increase / (decrease) in cash and cash equivalents	121.5	(66.6)
Cash, cash equivalents and current financial assets	273.9	207.2

(*)In the context of the preparation of its 2018 consolidated financial statements, the Company adjusted the financial statements previously published for the 2017 fiscal year under IFRS. More information is provided on Appendix 2 below.

The summary IFRS consolidated financial statements for the year ended December 31, 2018 are presented in the appendix at the end of this press release. The 2018 annual consolidated financial statements are available on the "Investors" page of the GENFIT website.

Key 2019 Events

- February 12, 2019: Frankfurt European Midcap Event (Frankfurt, Germany)
- February 25-26, 2019: Global NASH Congress (London, UK)
- February 27-March 1, 2019: Leerink Annual Global Healthcare Conference (New York, NY - USA)
- March 12-14, 2019: Barclays Global Healthcare Conference (Miami, FL - USA)

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APPENDIX 1

Annual Consolidated Financial Results at December 31, 2018
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The Statements of Financial Position, Statements of Operations and Statements of Cash Flow of the Company were prepared in accordance International Financial Reporting Standards (IFRS).

The audit procedures on the consolidated financial statements have been performed. The consolidated financial statements for the period ended December 31, 2018 were approved by Board of Directors on February 4, 2019 and will be submitted to the shareholders at the Shareholders' Meeting on June 13, 2019.

The full consolidated financial statements as well as the notes to the consolidated financial statements for the period ended December 31, 2018 are available on GENFIT's website under the "Investors" tab. The annual financial report, included in the registration document, will be available on GENFIT's website before the end of April 2019.

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Consolidated Statement of Financial Position

ASSETS (in € thousands)	As of	
	2017/12/31 (*)	2018/12/31
Non-current assets		
Intangible assets	636	796
Property, plant and equipment	6 324	7 764
Non-current trade and others receivables	1 921	1 489
Other non-current financial assets	729	1 313
Deferred tax assets	0	0
Total - Non-current assets	9 611	11 362
Current assets		
Inventories	4	4
Current trade and others receivables	7 955	8 794
Other current financial assets	31	0
Other current assets	1 761	2 078
Cash and cash equivalents	273 820	207 240
Total - Current assets	283 572	218 116
Total - Assets	293 183	229 478

SHAREHOLDERS' EQUITY AND LIABILITIES (in € thousands)	As of	
	2017/12/31 (*)	2018/12/31
Shareholders' equity		
Share capital	7 792	7 796
Share premium	251 932	251 554
Accumulated deficit	(102 531)	(158 897)
Currency translation adjustment	(8)	6
Net loss	(55 728)	(79 521)
Total shareholders' equity - Group share	101 457	20 939
Non-controlling interests	0	0
Total - Shareholders' equity	101 457	20 939
Non-current liabilities		
Non-current convertible loans	154 539	159 176
Other non-current loans and borrowings	6 978	7 255
Non-current deferred income and revenue	2	1
Non-current employee benefits	936	1 085
Deferred tax liabilities	2 165	1 773
Total - Non-current liabilities	164 620	169 291
Current liabilities		
Current convertible loans	1 329	1 312
Other current loans and borrowings	1 834	1 848
Current trade and other payables	23 580	35 974
Current deferred income and revenue	1	1
Current provisions	361	112
Total - Current liabilities	27 106	39 248
Total - Shareholders' equity & liabilities	293 183	229 478

(*)In the context of the preparation of its 2018 consolidated financial statements, the Company adjusted the financial statements previously published for the 2017 fiscal year under IFRS. More information is provided on Appendix 2 below.

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Statement of Operations

(in € thousands, except earnings per share data)	Year ended	
	2017/12/31(*)	2018/12/31
Revenues and other income		
Revenue	118	69
Other income	6 737	7 425
Revenues and other income	6 856	7 494
Operating expenses and other operating income (expenses)		
Research and development expenses	(54 189)	(67 024)
General and administrative expenses	(9 421)	(9 793)
Other operating income (expenses)	60	(162)
Operating loss	(56 695)	(69 484)
Financial income	642	728
Financial expenses	(3 096)	(11 118)
Financial loss	(2 453)	(10 391)
Net loss before tax	(59 148)	(79 875)
Income tax expense	3 420	354
Net loss	(55 728)	(79 521)
Attributable to owners of the Company	(55 728)	(79 521)
Attributable to non-controlling interests	0	0
Basic and diluted loss per share		
Basic loss per share (€/share)	(1.79)	(2.55)

(*)In the context of the preparation of its 2018 consolidated financial statements, the Company adjusted the financial statements previously published for the 2017 fiscal year under IFRS. More information is provided on Appendix 2 below.

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Statement of Cash Flows

(in € thousands)	Year ended 31/12/2017	Year ended 31/12/2018
Cash flows from operating activities		
+ Net loss	(55 728)	(79 521)
Reconciliation of net loss to net cash used in operating activities		
Adjustments for:		
+ Amortization	1 226	1 819
+ Depreciation and impairment charges	186	(208)
+ Expenses related to share-based compensation	278	787
- Gain / (loss) on disposal of property, plant and equipment	8	(2)
+ Net finance expenses	2 296	10 971
+ Income tax expense	(3 420)	(354)
+ Other non-cash items	17	0
Operating cash flows before change in working capital	(55 137)	(66 507)
Change in:		
Decrease / (increase) in inventories	10	(0)
Increase in trade receivables and other assets	(2 106)	(724)
Increase in trade payables and other liabilities	7 364	11 056
Change in working capital	5 268	10 332
Income tax paid	13	93
Net cash flows used in operating activities	(49 856)	(56 081)
Cash flows from investment activities		
- Acquisition of property, plant and equipment	(2 800)	(2 938)
+ Proceeds from disposal of property, plant and equipment	15	3
- Acquisition of financial instruments	(163)	(1 050)
+ Proceeds from sale of financial instruments	0	0
- Acquisition of subsidiary, net of cash acquired	0	0
Net cash flows used in investment activities	(2 948)	(3 986)
Cash flows from financing activities		
+ Proceeds from issue of share capital (net)	0	0
+ Proceeds from subscription / exercise of share warrants	37	37
+ Proceeds from new loans and borrowings net of issue costs	177 338	1 800
- Repayments of loans and borrowings	(1 655)	(2 000)
- Financial interests paid (including finance lease)	(1 372)	(6 351)
Net cash flows provided by / (used in) financing activities	174 348	(6 514)
Increase / (decrease) in cash and cash equivalents	121 544	(66 580)
Cash and cash equivalents at the beginning of the period	152 277	273 820
Cash and cash equivalents at the end of the period	273 820	207 240

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APPENDIX 2

Correction for Technical Errors on the Annual Consolidated Financial Results for the year ended December 31, 2017

In the context of the preparation of its 2018 consolidated financial statements, and in accordance with IAS 8, the Company adjusted the financial statements previously published for the 2017 fiscal year with respect to the accounting for the OCEANE issuance.

These changes were approved by the Board of Directors at its meeting on February 4, 2019.

These changes have no impact on the operating results or the cash position, and the impacts on the consolidated statements of operations, consolidated statements of financial position and the consolidated statements of changes in equity are presented below.

The following table shows the impact on the Net Income (Loss) for the 2017 fiscal year, compared to previously published figures:

	Year ended 2017/12/31 as published	Correction: proper effective interest rate of convertible loan	Correction: proper accounting under IAS 12	Year ended 2017/12/31 as corrected	See explanatory note below
(in € thousands, except earnings per share data)					
Revenues and other income					
Revenue	118			118	
Other income	6 737			6 737	
Revenues and other income	6 856	0	0	6 856	
Operating expenses and other operating income (expenses)					
Research and development expenses	(54 189)			(54 189)	
General and administrative expenses	(9 421)			(9 421)	
Other operating income (expenses)	60			60	
Operating loss	(56 695)	0	0	(56 695)	
Financial income	642			642	
Financial expenses	(2 168)	(928)		(3 096)	A
Financial loss	(1 526)	(928)	0	(2 453)	
Net loss before tax	(58 220)	(928)	0	(59 148)	
Income tax expense	(384)		3 804	3 420	B
Net loss	(58 604)	(928)	3 804	(55 728)	

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The corrections lead to an improvement in the net income (loss) of €2.9 million, bringing it to €(55.7) million compared to €(58.6) million in the previously published accounts.

The accounting changes are related to:

A	Financial expenses – Correction of the effective interest rate taken into account for the calculation of financial expenses related to the OCEANE at the transaction date of October 16, 2017 for an amount of €928k (increase of financial expenses).
B	Recognition of – A deferred tax liability related to the equity component of the OCEANE (€19,960k) for €5,648k, as a decrease of equity on October 16, 2017; – A deferred tax liability as of December 31, 2017 related to the tax deduction of the OCEANE issuance costs and the difference between the effective interest rate and the portion of deductible coupon (€120k net), as an increase of the financial expenses in net result (deferred tax expense); – A deferred tax asset arising from the use of net operating losses (NOLs) carried forward up to the deferred tax liabilities mentioned above, taking into account the French tax rule which limits considerations of such NOLs to 50% (above one million Euros), and the timing of reversal of these deferred tax liabilities, for an amount of €3,724k at the transaction date (deferred tax income), the use of NOLs for the period of €121k (deferred tax expense) and the reversal of the previously recognized deferred tax expense as of December 31, 2017 for €321k (decrease of deferred tax expense), resulting in an aggregate amount of €3,924k of reduction of deferred tax expense (or a net deferred tax income).

As a result, the net loss per share for the 2017 fiscal year decreased from €1.88 to €1.79.

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The following table shows the impact of the corrections of these errors in the consolidated statements of operations at December 31, 2017:

SHAREHOLDERS' EQUITY AND LIABILITIES (in € thousands)	As of 2017/12/31 as published	Correction: proper effective interest rate of convertible loan	Correction: proper accounting under IAS 12	As of 2017/12/31 as corrected	See explanatory note below
<u>Shareholders' equity</u>					
Share capital	7 792			7 792	
Share premium	257 580		(5 648)	251 932	C
Accumulated deficit	(102 531)			(102 531)	
Currency translation adjustment	(8)			(8)	
Net loss	(58 604)	(928)	3 804	(55 728)	D
Total shareholders' equity - Group share	104 229	(928)	(1 844)	101 457	
Non-controlling interests	0			0	
Total - Shareholders' equity	104 229	(928)	(1 844)	101 457	
<u>Non-current liabilities</u>					
Non-current convertible loans	153 611	928		154 539	E
Other non-current loans and borrowings	6 978			6 978	
Non-current deferred income and revenue	2			2	
Non-current employee benefits	936			936	
Deferred tax liabilities	321		1 844	2 165	F, G
Total - Non-current liabilities	161 848	928	1 844	164 620	
<u>Current liabilities</u>					
Current convertible loans	1 329			1 329	
Other current loans and borrowings	1 834			1 834	
Current trade and other payables	23 580			23 580	
Current deferred income and revenue	1			1	
Current provisions	361			361	
Total - Current liabilities	27 106	0	0	27 106	
Total - Shareholders' equity & liabilities	293 183	0	(0)	293 183	

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The balance sheet at December 31, 2017 was adjusted due to the following changes, in particular:

C	– The equity component of the OCEANE (€19,960k) determined in accordance with split accounting under IAS 32 was decreased by the deferred tax liability recognized under IAS 12 (€5,648k).
D	– The impact on income is the result of the elements explained in points A and B above.
E	– The non-current part of the convertible loan (OCEANE) is increased by the financial expenses calculated with the proper application of the effective interest rate.
F	– The correction of the initially recognized deferred tax liabilities under IAS 12 for €1,844k.
G	– Following these corrections, the deferred tax liabilities are €2,165k.

The overall impact of these corrections is a €2,772k decrease in equity and an increase in non-current liabilities in the same amount.

Additional details are provided in notes 6.2.3 to the 2018 consolidated financial statements available on GENFIT's website (www.genfit.com) under the "Investors" tab.

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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. Elafibranor also presents a particularly interesting profile to potentially treat PBC, a rare liver disease.

ABOUT NASH

Nonalcoholic steatohepatitis, or NASH, is a liver disease characterized by an accumulation of fat, inflammation and degeneration of hepatocytes, and may ultimately lead to life-threatening conditions like cirrhosis, liver failure or liver cancer requiring liver transplant.

ABOUT PBC

Primary biliary cholangitis, or PBC, is a chronic disease in which bile ducts in the liver are gradually destroyed. The damage to bile ducts can inhibit the liver's ability to rid the body of toxins, and can lead to scarring of liver tissue known as cirrhosis.

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 almost two decades. Its most advanced drug candidate, elafibranor, is currently evaluated in pivotal Phase 3 clinical trial ("RESOLVE-IT") as a potential treatment for nonalcoholic steatohepatitis, or NASH. NASH is considered by regulatory authorities as a medical emergency because of its potentially severe consequences, although often asymptomatic until late stages, and because its prevalence is on the rise. Elafibranor has also obtained positive preliminary results in a Phase 2 clinical trial in primary biliary cholangitis (PBC), a severe chronic liver disease. As part of GENFIT's comprehensive approach to clinical management of NASH patients, the company is also developing a new, non-invasive and easy-to-access blood-based *in vitro* diagnostic, or IVD, test to identify patients with NASH who may be appropriate candidates for drug therapy. With facilities in Lille and Paris, France, and Cambridge, MA, USA, the Company has approximately 150 employees. GENFIT is a public company listed in

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compartment B of Euronext's regulated market in Paris (Euronext: GNFT - ISIN: FR0004163111).
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 safety, biomarkers, progression of, and results from, its ongoing and planned clinical trials, including its RESOLVE-IT Phase 3 trial, review and approvals by regulatory authorities, such as the FDA or the EMA, of its drug and diagnostic candidates, the success of any in-licensing 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 in Section 4 "Main Risks and Uncertainties" of the Company's 2017 Registration Document registered with the French Autorité des Marchés Financiers on April 27, 2018 under n° R.18-032, which is available on GENFIT's website (www.GENFIT.com) and on the website of the AMF (www.amf-france.org) and as updated by the 2018 Half Year Business and Financial Report and available on the Investors page of GENFIT's website. 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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