

2020 Full-Year Results: Major advances in NASH and significantly extended cash runway through successful IPO in the United States

- Publication of positive topline results from the NATIVE Phase IIb clinical trial evaluating lanifibranor in NASH and decision to move into pivotal Phase III development
- ► Breakthrough Therapy Designation granted to lanifibranor in NASH by the U.S. Food and Drug Administration (FDA)
- ► Finalization of Phase III clinical trial design with lanifibranor in NASH following end-of-phase II meeting with the FDA and receipt of Scientific Advice letter from the European Medicines Agency (EMA)
- Expansion into the United States with appointment of Dr. Michael Cooreman, M.D., as Chief Medical Officer and opening of U.S. subsidiary
- ► Announcement of timeline for Phase III clinical trial evaluating lanifibranor in NASH
- ➤ Confirmation by the FDA that the toxicology package regarding lanifibranor is complete and acceptable to support the filing of a New Drug Application (NDA) for the treatment of NASH and improvement of liver fibrosis
- ➤ Completion of World Health Organization's (WHO) International Nonproprietary Names (INN) process by AbbVie for ABBV-157, now named cedirogant
- Cash position¹ at €113.0m as of December 31, 2020 compared to €35.8m as of December 31, 2019
- Successful €94.9m² initial public offering (IPO) on the Nasdaq Global Market in the U.S, extending the Company's cash runway through Q4 2022

¹ The cash position includes cash and cash equivalents as well as short-term deposits which are included in the category "other current assets" in the IFRS statement of financial position as of December 31, 2020. In fiscal year 2020, the increase in short-term deposits is included in the category "net cash flows from investing activities" in the IFRS cash flow statement.

² Based on an exchange rate of \$1.1342 per euro, the exchange rate published by the European Central Bank on July 9, 2020.



Daix (France), March 4, 2021 – Inventiva (Euronext Paris and Nasdaq: IVA), a clinical-stage biopharmaceutical company focused on the development of oral small molecule therapies for the treatment of non-alcoholic steatohepatitis (NASH), mucopolysaccharidoses (MPS) and other diseases with significant unmet medical need, today reported its full-year results for 2020.

Frédéric Cren, Chairman, CEO and cofounder of Inventiva, stated: "2020 has truly been one of the most transformative years since the establishment of Inventiva in 2012, driven by a series of major achievements. Following very promising results from our NATIVE Phase IIb clinical trial in NASH and the U.S. FDA 'Breakthrough Therapy' designation of lanifibranor, the FDA and EMA have given us their green light to initiate the pivotal Phase III trial with our lead drug candidate, the design of which we have finalized in the beginning of this year. Based on these milestones, clearly confirming the potential of lanifibranor to become a reference treatment for NASH, we have decided to focus our efforts on this particular program while, in parallel, evaluating all options to optimize the development of our second clinical-stage asset odiparcil in MPS VI. At the same time, we were able to significantly extend our cash runway and boost our visibility in the United States thanks to the success of our IPO on the Nasdaq Global Market. Together with the appointment of Dr. Michael Cooreman as Chief Medical Officer and the very recent opening of Inventiva's subsidiary in the United States, we are on track to initiate the Phase III clinical trial with lanifibranor in NASH in the first half of this year."

Key financial results

Inventiva's key financial figures for its 2020 full-year results are as follows:

As of December 31, 2020, the Company's cash position³ (excluding exchange rate effects) stood at €113.0 million compared to €124.6 million as of September 30, 2020, and €35.8 million as of December 31, 2019.

- In 2020, net cash used in operating activities amounted to (€30.6) million compared to (€28.4) million in 2019. This increase was mainly due to higher general and administrative and non-recurrent expenses incurred during the second half of the year linked to the Company's IPO in the U.S. and listing on Nasdaq. These costs have been partly offset by the savings generated from the halt of the clinical development of lanifibranor in systemic sclerosis in 2019 and the Employment Safeguard Plan subsequently introduced mid-2019, as well as, to a lesser extent, the successful conclusion of the NATIVE Phase IIb clinical study in NASH in June 2020. Furthermore, the cash flow from operating activities was positively impacted by the receipt of €4.2 million in respect of the 2018 Research Tax Credit (CIR Crédit Impôt Recherche) in January 2020, and the receipt of €4.2 million in total in respect of the 2019 Research Tax Credit in April and June 2020. In 2019, Inventiva recorded the payment of €3.6 million of the 2017 Research Tax Credit, the €3.5 million milestone payment from AbbVie following the enrollment of the first psoriasis patient in the clinical study underway with ABBV-157 and the last payment from Boehringer Ingelheim as part of its collaboration with the Company.
- Net cash from investing activities (excluding the variation in short-term deposits) remained stable in 2020 compared to 2019 and amounted to (€0.9) million.
- Finally, net cash from financing activities amounted to €111.7 million in 2020 compared to €8.4 million in 2019, driven by: the issuance of €15.0 million (gross proceeds) of ordinary shares to certain existing investors in the Company in February 2020, the entry into a €10.0 million credit agreement, guaranteed by the French State, with a syndicate of French banks in May 2020, and the receipt of €94.9 million⁴ (gross proceeds) following the Company's successful U.S. IPO in July 2020, extending Inventiva's cash runway through the fourth quarter of 2022.

³ The cash position includes cash and cash equivalents as well as short-term deposits which are included in the category "other current assets" in the IFRS statement of financial position as of December 31, 2020. In fiscal year 2020, the increase in short-term deposits is included in the category "net cash flows from investing activities" in the IFRS cash flow statement.

⁴ Based on an exchange rate of \$1.1342 per euro, the exchange rate published by the European Central Bank on July 9, 2020.



In 2020, Inventiva's **revenues** amounted to €0.4 million compared to €7.0 million in 2019. While Inventiva did not expect to generate any revenues in 2020, this decrease was driven by the Company recording the payment of €3.5 million under its collaboration with AbbVie in December 2019, the revenues of €2.6 million under its collaboration with Boehringer Ingelheim in November 2019, including the payment of €0.5 million and the €2.1 million write back entry, in accordance with IFRS 15 "Revenue from Contracts with Customer", following the end of this research collaboration after Inventiva fulfilled all its commitments.

Other income amounted to €4.9 million in 2020 versus €4.3 million in 2019, up 14%, mainly driven by the receipt of the 2018 and 2019 Research Tax Credit.

R&D expenses amounted to €23.7 million in 2020 versus €33.8 million in 2019, down 29%. These expenses were mainly dedicated to the development of lanifibranor in NASH and odiparcil in MPS VI. The decrease compared to the previous year was mainly due to the halt of the clinical development of lanifibranor in systemic sclerosis in February 2019 and the savings generated by the Employment Safeguard Plan subsequently introduced, with 2020 recording the full effect of the savings generated. In addition, while the Company had recorded R&D expenses related to the NATIVE Phase IIb clinical trial in NASH for the entire fiscal year in 2019, Inventiva did not record as significant clinical development expenses in the second half of 2020 as in the first half of 2020 given the successful conclusion of the NATIVE Phase IIb trial in June 2020.

General and administrative expenses amounted to €8.5 million in 2020 compared to €6.1 million in 2019, primarily driven by expenses related to the preparation of the Company's IPO in the U.S. and the increased operational recurring expenses linked to Inventiva's dual listing status following its listing on Nasdaq.

Other operating income (expenses) amounted to €2.2 million in 2020 compared to €1.5 million in 2019. The first half of 2019 took into account the recording of a provision of €1.1 million relating to the Employment Safeguard Plan, while 2020 recorded non-recurring expenses incurred as part of the IPO in the U.S., not reflected in the share premium of issued shares, and a non-recurring net income related to the Research Tax Credit of previous years.

Due to the unfavourable exchange rate between USD and Euro following the Company's IPO in the U.S. and listing on Nasdaq in July 2020, Inventiva has incurred a net financial loss of €3.9 million.

The Company' **net loss** stood at €33.6 million in 2020 compared to a loss of €30.2 million in 2019.

The following table presents Inventiva's income statement, prepared in accordance with IFRS, for the 2020 financial year, with comparatives for the 2019 financial year:

(in thousands of euros, except share and per share amounts)	December 31, 2020	December 31, 2019
Revenues	372	6,998
Other income	4,891	4,293
Research and development expenses	(23,717)	(33,791)
Marketing – business development expenses	(563)	(249)
General and administrative expenses	(8,499)	(6,088)
Other operating income (expenses)	(2,202)	(1,475)
Net operating loss	(29,718)	(30,312)
Net financial income (loss)	(3,902)	93



Income tax	-	-
Net loss for the period	(33,619)	(30,218)
Basic / diluted loss per share (euros/share)	(0.99)	(1.28)
Weighted average number of outstanding shares used for computing basic/diluted loss per share	33,874,751	23,519,897

Announcement of the timeline for the Phase III clinical trial with lanifibranor in NASH

Inventiva is progressing on the initiation of its NATIV3 (NASH lanifibranor Phase 3 trial) Phase III clinical trial evaluating lanifibranor in NASH, and has defined the following timeline for Part 1 of the study⁵:

- First site active expected for the second quarter of 2021
- First Patient First Visit expected in the third quarter of 2021
- Last Patient First Visit expected in the second half of 2022
- Last Patient Last Visit expected in the first half of 2024
- Publication of headline results expected in the second half of 2024

Update on non-clinical toxicology data regarding lanifibranor

During a type B meeting with the FDA, the regulatory body has confirmed that the non-clinical toxicology package available for lanifibranor is both complete and acceptable to support the filing of a NDA for the targeted indication of treatment of NASH and improvement of liver fibrosis. The package includes the results of two-year carcinogenicity studies in mice and rats as well as long-term toxicology studies of up to one year in monkeys.

<u>Update of the timeline for the Phase II clinical trial with lanifibranor in type 2 diabetes patients (T2DM) with Non-Alcoholic Fatty Liver Disease (NAFLD)</u>

The COVID-19 pandemic has had a large impact on patient enrollment during 2020. In this context, the publication of the study results are now expected in the first half of 2022 versus 2021 as previously announced.

Update on the collaboration with AbbVie in auto-immune diseases

Following the completion of the WHO INN process by AbbVie, the name of "cedirogant" has been attributed to ABBV-157, the selective and orally-available ROR-y inverse agonist jointly discovered with AbbVie for the treatment of auto-immune diseases.

Due to the current COVID-19 context, the cedirogant Phase I clinical study in psoriasis patients led by AbbVie is now expected to read out in the second quarter of 2021 compared to the first quarter of 2021 as previously announced.

⁵ Part 1 of the study refers to a 72-week treatment in approximately 900 patients allowing to seek accelerated approval in the U.S. and conditional approval in the EU for lanifibranor based on a pre-specified histology analysis. This part of the study is followed by an extension period (Part 2), the end date of which depends on a pre-defined number of clinical events. For more information, please refer to Inventiva's corporate presentation, accessible here: https://inventivapharma.com/investors/investor-presentations/.



Main areas of progress in the R&D portfolio

Lanifibranor in non-alcoholic steatohepatitis (NASH)

- Launch of a collaboration with Professor Jérôme Boursier, M.D., Ph.D, Professor of Medicine at the Faculty of Medicine of Angers University, to develop one or several non-invasive biomarkers or a composite non-invasive biomarker score to identify patients responding to lanifibranor with regards to NASH resolution and fibrosis improvement February 25, 2021
- Finalization of the design of the pivotal Phase III clinical trial with lanifibranor in NASH following the receipt
 of the Scientific Advice letter from the EMA; confirmation of the initiation of the trial in the first half of 2021

 January 5, 2021
- Publication of new pre-clinical data on lanifibranor for the treatment of cirrhosis by the peer-reviewed scientific journal *Journal of Hepatology*, showing the beneficial effects of its mechanism of action on portal hypertension and hepatic fibrosis in experimental advanced chronic liver disease (ACLD) – *December 7, 2020*
- Conclusions from Inventiva's end-of-phase II meeting with the U.S. FDA for lanifibranor following the publication of positive topline results from its NATIVE Phase IIb clinical trial in NASH – November 10, 2020
- Receipt of the U.S. FDA "Breakthrough Therapy" designation for lanifibranor in NASH enabling the Company to expedite the development and review of the drug candidate – October 12, 2020
- Decision by Professor Kenneth Cusi, the investigator of the ongoing Phase II clinical trial evaluating lanifibranor in T2DM patients with NAFLD, to reduce the number of patients following higher than expected observed effects of lanifibranor in reducing steatosis during the NATIVE Phase IIb clinical trial in NASH July 6, 2020
- Publication of positive topline results from the NATIVE Phase IIb clinical trial; decision to continue the clinical development of lanifibranor in NASH and enter into pivotal Phase III development – June 15, 2020
- Approval of a new patent protecting the use of lanifibranor for the treatment of several fibrotic diseases, including NASH, in China until June 2035 by the China National Intellectual Property Administration (CNIPA) May 25, 2020

Odiparcil in mucopolysaccharidosis type VI (MPS VI)

- Decision to review all available options to optimize the development of second clinical-stage asset odiparcil
 for the treatment of MPS VI; suspension of all MPS-related R&D activities during such time November 10,
 2020
- Receipt of the U.S. FDA "Fast Track" designation for odiparcil in MPS VI October 19, 2020
- Acceptance of the "Investigational New Drug" (IND) application for odiparcil in MPS VI by the U.S. FDA August 10, 2020
- Decision by Inventiva to extend the duration of the Phase I/II SAFE-KIDDS (SAFEty, pharmacoKinetics and pharmacoDynamics, Dose escalating Study) clinical trial evaluating odiparcil in MPS VI children from 6 to 12 months following a scientific advice meeting with the EMA – July 23, 2020
- Publication of latest data on odiparcil's mechanism of action in the leading scientific journal PLOS ONE, showing that the drug candidate was associated with decreased glycosaminoglycan (GAG) accumulation and



increased GAG excretion, and highlighting its distribution in MPS VI disease-relevant tissues and organs – *May* 18, 2020

Other significant milestones

- Opening of Inventiva's subsidiary in the United States ahead of the initiation of the pivotal Phase III clinical trial with lanifibranor in NASH *January*, 6, 2021
- Appointment of Dr. Michael Cooreman, M.D., as Inventiva's Chief Medical Officer to succeed Dr. Marie-Paule Richard, M.D., who has decided to take her retirement as of December 17, 2020 – November 5, 2020
- Appointment of Dr. Arun J. Sanyal to Inventiva's Scientific Advisory Board, further strengthening the Board's expertise in the field of NASH – July 29, 2020
- Successful €94.9⁶ million IPO on the Nasdaq Global Market in the United States, extending Inventiva's cash runway through the fourth quarter of 2022 July 15, 2020
- Entry into a €10.0 million non-dilutive loan facility guaranteed by the French State ("Prêt Garanti par l'Etat"), with the support of Bpifrance, Crédit Agricole Champagne-Bourgogne and Société Générale, contributing to strengthening the Company's cash position in the context of the COVID-19 pandemic May 19, 2020
- Capital increase of €15 million subscribed by BVF Partners L.P., New Enterprise Associates (NEA), Novo Holdings A/S and Sofinnova Partners – February 11, 2020

Next key milestones expected

- Initiation of NATIV3 Phase III clinical trial evaluating lanifibranor in NASH planned in the first half of 2021
- AbbVie's completion of its ongoing Phase I clinical trial with cedirogant (ABBV-157) in psoriasis patients expected in the second quarter of 2021
- Strategy update on the development of odiparcil planned in 2021

Upcoming investor conference participation

- H.C. Wainwright Virtual Global Life Sciences Conference, March 9-10, 2021
- 33rd Virtual Roth Conference, March 15-17, 2021
- 7th Annual Truist Securities 2021 Life Sciences Summit, May 4-5, 2021
- Jefferies Virtual Healthcare Conference, June 1-3, 2021

Upcoming scientific conference participation

International Liver Congress™ 2021, June 23-26, 2021

⁶ Based on an exchange rate of \$1.1342 per euro, the exchange rate published by the European Central Bank on July 9, 2020.



Conference call

A conference call in English will be held tomorrow, Friday, March 5, 2021 at 2:00 pm (Paris time). To join the conference call, please use the code 3586531 after dialing one of the following numbers:

France: +33 (0) 1 70 70 07 81 Belgium: +32 (0) 2 793 3847 Germany: +49 (0) 69 2222 2625 Netherlands: +31 (0) 20 795 6614 Switzerland: +41 (0) 44 580 7145 United Kingdom: +44 (0) 207 192 8338 United States: +1 646-741-3167

The presentation accompanying this conference call will be available on Inventiva's website from 2:00 pm (Paris time) tomorrow, Friday, March 5, 2021 onwards in the "Investors" – "Financial Results & Presentations" section and can be followed live at: https://edge.media-server.com/mmc/p/wr8srgzq.

A replay of the conference call and the presentation will be available after the event at: http://inventivapharma.com/investors/financial-results-presentations/.

Next financial results publication

Revenues and cash position for the first quarter of 2021: Thursday, May 13, 2021 (after U.S. market close)

About Inventiva

Inventiva is a clinical-stage biopharmaceutical company focused on the development of oral small molecule therapies for the treatment of NASH, MPS and other diseases with significant unmet medical need.

Leveraging its expertise and experience in the domain of compounds targeting nuclear receptors, transcription factors and epigenetic modulation, Inventiva is currently advancing two clinical candidates, as well as a deep pipeline of earlier stage programs.

Lanifibranor, its lead product candidate, is being developed for the treatment of patients with NASH, a common and progressive chronic liver disease for which there are currently no approved therapies. In 2020, Inventiva announced positive topline data from its Phase IIb clinical trial evaluating lanifibranor for the treatment of patients with NASH and obtained Breakthrough Therapy and Fast Track designation for lanifibranor in the treatment of NASH.

Inventiva is also developing odiparcil, a second clinical stage asset, for the treatment of patients with subtypes of MPS, a group of rare genetic disorders. Inventiva announced positive topline data from its Phase IIa clinical trial evaluating odiparcil for the treatment of adult MPS VI patients at the end of 2019 and received FDA Fast Track designation in MPS VI for odiparcil in October 2020.

In parallel, Inventiva is in the process of selecting an oncology development candidate for its Hippo signalling pathway program. Furthermore, the Company has established a strategic collaboration with AbbVie in the area of autoimmune diseases. AbbVie has started the clinical development of ABBV-157, a drug candidate for the treatment of moderate to severe psoriasis resulting from its collaboration with Inventiva. This collaboration enables Inventiva to receive milestone payments upon the achievement of pre-clinical, clinical, regulatory and commercial milestones, in addition to royalties on any approved products resulting from the collaboration.



The Company has a scientific team of approximately 70 people with deep expertise in the fields of biology, medicinal and computational chemistry, pharmacokinetics and pharmacology, as well as in clinical development. It also owns an extensive library of approximately 240,000 pharmacologically relevant molecules, approximately 60% of which are proprietary, as well as a wholly-owned research and development facility.

Inventiva is a public company listed on compartment C of the regulated market of Euronext Paris (ticker: IVA - ISIN: FR0013233012) and on the Nasdaq Global Market in the United States (ticker: IVA). www.inventivapharma.com

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Important Notice

This press release contains forward-looking statements, forecasts and estimates with respect to Inventiva's clinical trials, clinical trial data releases, clinical development plans and anticipated future activities of Inventiva. Certain of these statements, forecasts and estimates can be recognized by the use of words such as, without limitation, "believes", "anticipates", "expects", "intends", "plans", "seeks", "estimates", "may", "will" and "continue" and similar expressions. Such statements are not historical facts but rather are statements of future expectations and other forward-looking statements that are based on management's beliefs. These statements reflect such views and assumptions prevailing as of the date of the statements and involve known and unknown risks and uncertainties that could cause future results, performance or future events to differ materially from those expressed or implied in such statements. Actual events are difficult to predict and may depend upon factors that are beyond Inventiva's control. There can be no quarantees with respect to pipeline product candidates that the clinical trial results will be available on their anticipated timeline, that future clinical trials will be initiated as anticipated, or that candidates will receive the necessary regulatory approvals. Actual results may turn out to be materially different from the anticipated future results, performance or achievements expressed or implied by such statements, forecasts and estimates, due to a number of factors, including that Inventiva has incurred significant losses since inception, Inventiva has a limited operating history and has never generated any revenue from product sales, Inventiva will require additional capital to finance its operations, Inventiva's future success is dependent on the successful clinical development, regulatory approval and subsequent commercialization of current and any future product candidates, preclinical studies or earlier clinical trials are not necessarily predictive of future results and the results of Inventiva's clinical trials may not support Inventiva's product candidate claims, Inventiva may encounter substantial delays in its clinical trials or Inventiva may fail to demonstrate safety and efficacy to the satisfaction of applicable regulatory authorities, enrollment and retention of patients in clinical trials is an expensive and time-consuming process and could be made more difficult or rendered impossible by multiple factors outside Inventiva's control, Inventiva's product candidates may cause undesirable side effects or have other properties that could delay or prevent their regulatory approval, or limit their commercial potential, Inventiva faces substantial competition and Inventiva's business, preclinical studies and clinical development programs and timelines, its financial condition and results of operations could be materially and adversely affected by the current COVID-19 pandemic. Given these risks and uncertainties, no representations are made as to the accuracy or fairness of such forward-looking statements, forecasts and estimates. Furthermore, forward-looking statements,



forecasts and estimates only speak as of the date of this press release. Readers are cautioned not to place undue reliance on any of these forward-looking statements.

Please refer to the Universal Registration Document filed with the Autorité des Marchés Financiers on June 19, 2020 under n° D.20-0551 and its amendment filed on July 10, 2020 under n° D. 20-0551-A01 as well as the half-year financial report on June 30, 2020 for additional information in relation to such factors, risks and uncertainties.

Except as required by law, Inventiva has no intention and is under no obligation to update or review the forward-looking statements referred to above. Consequently, Inventiva accepts no liability for any consequences arising from the use of any of the above statements.