

## Inventiva reports its 2021 Full-Year Results: key milestones achieved with lanifibranor in NASH and cedirogant in psoriasis

- ▶ Initiation of the NATiv3 Phase III clinical trial with lanifibranor in NASH
- ▶ Receipt of a €4 m milestone payment from AbbVie following the inclusion of the first patient in the ongoing Phase IIb clinical trial with cedirogant<sup>1</sup> in patients with moderate to severe psoriasis
- ▶ R&D expenses doubled for full year 2021 reaching €48.4 m compared to 2020, mainly driven by the preparation and initiation of the NATiv3 Phase III clinical trial
- ▶ Cash position<sup>2</sup> at €95.4 m as of December 31, 2021 compared to €113.0 m as of December 31, 2020
- ▶ Implementation of an At-The-Market (“ATM”) program in the United States for the sale up to \$100 m of ADS

**Daix (France), Long Island City (New York, United States), March 7, 2022** – 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) and other diseases with significant unmet medical needs, today reported its full-year results for 2021.

**Frédéric Cren, Chairman, CEO and cofounder of Inventiva, stated:** “We are extremely proud of the strong progress of our clinical pipeline which has now two advanced clinical programs: a Phase III clinical trial in NASH with lanifibranor and a Phase IIb trial in patients with psoriasis initiated and fully financed by our partner AbbVie with cedirogant. Inventiva also announced the design of LEGEND, a Phase II combination trial with lanifibranor and SGLT2 inhibitor empagliflozin in patients with NASH and type 2 diabetes and we are looking forward to the results of our Phase II clinical trial in patients with type 2 diabetes and NAFLD expected in the second half of 2022. Furthermore, we believe the publication of our NATIVE Phase IIb clinical trial results by *The New England Journal of Medicine* strengthened the legitimacy of lanifibranor as a potential key treatment in NASH.

*In addition, we have strengthened our financial position with existing and new institutional investors, notably with the sale of approximately \$32 million of ADS via our ATM program in September. We have also received a €4 million milestone payment from our partner AbbVie, in connection with the cedirogant Phase IIb initiation, further supporting Inventiva’s cash position of €95.4 million as of December 31, 2021.*

*This combination of our clinical development advancement and financial results underpins our great confidence in Inventiva’s future. Lanifibranor which we believe has the potential to be a promising treatment for patients*

<sup>1</sup> Cedirogant is a clinical stage RORγ inverse agonist co-discovered by Inventiva with potential in several auto-immune diseases.

<sup>2</sup> The cash position is defined as cash and cash equivalents as well as short-term deposits which are included in the category “other current assets” in the IFRS consolidated statement of financial position as of December 31, 2021, but are considered by the Company as liquid and easily available.

suffering from NASH, and cedirogant having the potential to be a promising treatment for patients with moderate to severe psoriasis, could potentially provide important sources of revenues for us in the future.”

### Key financial results

Inventiva’s key financial results for its 2021 full-year results are as follows:

**As of December 31, 2021, the Company’s cash position stood at €95.4 million compared to €105.7 million as of September 30, 2021, and €113.0 million as of December 31, 2020.**

- For the full year 2021, **net cash used in operating activities** amounted to (€47.6) million, compared to (€30.6) million for 2020, mainly driven by the strong increase in R&D expenses linked to the costs associated with the preparation and initiation of the NATiV3 Phase III clinical trial with lanifibranor in NASH.
- **Net cash used from investing activities** (excluding the increase in short-term deposits of €1.4 million for the 2021 full year and €7.7 million for 2020) amounted to (€0.5) million for the full year 2021, a slight decrease compared to (€0.9) million in 2020.
- Finally, **net cash from financing activities** for the full year 2021 amounted to €25.4 million, mainly due to the sale of \$31.9 million (or €27.3 million<sup>3</sup>) in gross proceeds of the Company’s American Depositary Shares in the third quarter of 2021. The sales were made through the Company’s At-The-Market program established on August 2, 2021, to existing and new institutional investors. For the same period in 2020, net cash generated from financing activities amounted to €111.7 million, driven by the issuance of €15 million (gross proceeds) of ordinary shares to certain existing investors in the Company, the entry into €10 million in French state-guaranteed credit agreements with a syndicate of French banks, and the receipt of €94.9 million (gross proceeds) following the Company’s initial public offering on the Nasdaq Global Market in July 2020.

For the 2021 fiscal year, the Company recorded a positive exchange rate effect on cash and cash equivalents of €4.8 million.

Considering its current R&D and clinical development programs and excluding any potential additional financial resources that may originate from potential funding activities, the Company estimates that its cash, cash equivalents and short-term deposits should allow the Company to fund its operations through the first quarter of 2023<sup>4</sup>.

For the 2021 fiscal year, Inventiva’s **revenues** amounted to €4.2 million compared to €0.4 million for 2020 primarily due to the payment to the Company of €4.0 million for a milestone reached at the end of 2021, and received on January 31, 2022, following the launch by AbbVie of the Phase IIb clinical trial with cedirogant in the fourth quarter of 2021. As part of its collaboration with AbbVie in auto-immune diseases on cedirogant, Inventiva is eligible to receive potential development, regulatory and commercial milestone payments as well as royalty payments from AbbVie.

**Other income** amounted to €4.3 million for the 2021 fiscal year versus €4.9 million for 2020, down 11.9% mainly driven by the level of eligible expenses for an R&D tax credit.

<sup>3</sup> Based on the U.S. dollar euro exchange rates published by the European Central Bank on the sale dates.

<sup>4</sup> This estimate is based on the Company’s current business plan and excludes any potential milestones payable to or by the Company and any additional expenditures related to the potential continued development of the odiparcil program or resulting from the potential in-licensing or acquisition of additional product candidates or technologies, or any associated development the Company may pursue.

**R&D expenses** doubled for the fiscal year ended December 31, 2021 €48.4 million compared to €23.7 million for the same period in 2020, mainly driven by the costs associated with the preparation and initiation of the NATIV3 Phase III clinical trial with lanifibranor in NASH in the second half of 2021.

**General and administrative expenses (G&A)** amounted to €11.2 million for the fiscal year ended December 31, 2021, an increase of 31% compared to €8.5 million for the same period in 2020, mainly due to higher compliance costs resulting from Inventiva's first full fiscal year as a dual listed company in 2021.

**Other operating income (expenses)** stood at (€0.6) million for the fiscal year ended December 31, 2021 compared to (€2.2) million for the same period in 2020. The lower expenses incurred in 2021 included costs related to the preparation of the At-the-Market program and the amortization costs of the one-off Public Offering of Securities Insurance covering the Company's initial public offering on the Nasdaq Global Market compared to the total costs related to Nasdaq Global Market listing in 2020.

**Net income** amounted to €2.8 million for the 2021 fiscal year, compared to a net financial loss of €3.9 million for 2020, mainly linked to exchange rate variation.

The Company's **net loss** stood at €49.6 million as of December 31, 2021 compared to €33.6 million as of December 31, 2020.

The following table presents Inventiva's income statement, prepared in accordance with IFRS, for the 2021 financial year, with comparatives for the 2020 financial year:

*(in thousands of euros, except share and per share amounts)*

	<b>December 31, 2021</b>	<b>December 31, 2020</b>
<b>Revenues</b>	<b>4 194</b>	<b>372</b>
Other income	4 307	4 891
Research and development expenses	(48 452)	(23 717)
Marketing — Business development expenses	(364)	(563)
General and administrative expenses	(11 156)	(8 499)
Other operating income (expenses)	(644)	(2 202)
<b>Operating profit (loss)</b>	<b>(52 114)</b>	<b>(29 718)</b>
Financial income	5 478	2 057
Financial expenses	(2 635)	(5 959)
<b>Financial income (loss)</b>	<b>2 843</b>	<b>(3 902)</b>
Income tax	(364)	-
<b>Net loss for the period</b>	<b>(49 635)</b>	<b>(33 619)</b>
<b>Basic / diluted loss per share (euros/share)</b>	<b>(1,27)</b>	<b>(0,99)</b>
Weighted average number of outstanding shares used for computing basic/diluted loss per share	39 168 152	33 874 751

## Main areas of progress in the R&D portfolio

### Lanifibranor in non-alcoholic steatohepatitis (NASH)

- Publication of positive results of a clinical thorough QT/QTc<sup>5</sup> study demonstrating the safety of lanifibranor on cardiac electrical activity. The trial was conducted in accordance with U.S Food and Drug Administration guidance (FDA) in 217 patients to evaluate the potential effect of lanifibranor on the QT/QTc interval in healthy subjects and to support lanifibranor New Drug Application (NDA) package in NASH – *December 6, 2021*
- Publication of the study design of LEGEND, a multi-center, randomized, placebo-controlled proof-of-concept Phase IIa combination trial to assess the safety and efficacy of lanifibranor in combination with the SGLT2 inhibitor empagliflozin for the treatment of patients with type 2 diabetes (T2D) and non-cirrhotic NASH. A total of 63 patients are expected to be selected for the trial in several sites in the United States and Europe. The initiation of the trial is planned for the first half of 2022 and the publication of top line results is expected for the second half of 2023 – *October 27, 2021*
- Publication of the results of the NATIVE Phase IIb clinical trial with lanifibranor for the treatment of NASH in the peer-reviewed medical journal *The New England Journal of Medicine* (NEJM). The results showed that lanifibranor met both the primary and key secondary endpoints, including the composite endpoint of NASH resolution and improvement of liver fibrosis – *October 20, 2021*
- Receipt of the U.S. FDA “Fast Track” designation, previously granted to lanifibranor in NASH, encompasses the treatment of NASH patients with compensated cirrhosis – *September 21, 2021*
- Initiation of the NATIV3 Phase III clinical trial evaluating lanifibranor in adult patients with non-cirrhotic NASH and F2/F3 stage of liver fibrosis, with the activation of the first clinical sites in the United States and the start of patient screening – *September 8, 2021*

### Odiparcil in mucopolysaccharidosis type VI (MPS VI)

- Inventiva continues to review available options for the potential development of its second clinical-stage asset odiparcil for the treatment of MPS VI. All MPS-related R&D activities remain on hold pending the outcome of this review process expected to conclude in 2022<sup>6</sup>.

### Collaboration with AbbVie on cedirogant in autoimmune diseases

- Receipt of a €4 million milestone payment from AbbVie following the inclusion of the first patient in the ongoing Phase IIb clinical trial with cedirogant (previously ABBV-157) in patients with moderate to severe psoriasis – *January 31, 2022*
- Decision by AbbVie to initiate a Phase IIb clinical trial with cedirogant in patients with moderate to severe psoriasis after AbbVie reported showing promising activity as an oral psoriasis agent during its Phase Ib clinical trial – *May 12, 2021*

<sup>5</sup> The QT interval is the time between the Q and T waves on an electrocardiogram. It quantifies the time between the onset of depolarization of myocardial cells and their repolarization. A classic side effect of many classes of drugs is the prolongation of this QT interval.

<sup>6</sup> Please refer to Inventiva’s press release entitled “Inventiva receives positive FDA feedback to advance its lead drug candidate lanifibranor into pivotal Phase III in NASH” and published on November 10, 2020.

### Other significant milestones

- Sales of 2,083,334 of American Depositary Shares pursuant to the Company's ATM program established on August 2, 2021. The sales were issued to existing and new institutional investors– *September 23, 2021*
- Recruitments to reinforce Inventiva's clinical expertise, medical team and corporate functions, as well as its presence in France and the United States – *September 16, 2021*
- Implementation of an ATM program in the United States for the sale of up to \$100 million– *August 2, 2021*
- Appointment of Martine Zimmerman as Independent Director to Inventiva's Board of Directors to replace Nawal Ouzren. Martine Zimmerman's appointment will be submitted to Inventiva's shareholders for ratification at the Company's next Combined Shareholders' Meeting – *April 19, 2021*

### Anticipated potential key milestones

- Activation of first clinical sites for Phase IIa combination trial with lanifibranor and SGLT2 inhibitor empagliflozin in patients with NASH and T2D – *planned for the first half of 2022*
- Last Patient First Visit of the NATiV3 Phase III clinical trial evaluating lanifibranor in NASH – *planned for the second half of 2022*
- Publication of the results of the Phase II clinical trial evaluating lanifibranor for the treatment of NAFLD in patients with T2D – *planned for the second half of 2022*
- Strategy update on the potential development of odiparcil – *planned for 2022*

### Upcoming investor conference participation

- Cowen 42<sup>nd</sup> Annual Health Care Conference, *March 7-9, 2022*
- Invest securities Biomed Event, *March 8, 2022*
- H.C. Wainwright Annual Global Life Sciences Conference, *May 23-25, 2022*
- Jefferies 2021 Healthcare Conference, *June 8-10, 2022*

### Upcoming scientific conference participation

- International Conference on Fatty Liver – *April 28-30, 2022*

### Conference call

A **conference call** in English will be held **tomorrow, Tuesday, March 8, 2022 at 2:00 pm (Paris time)**. To join the conference call, please use the code **8738647** after dialing one of the following numbers:

France: +33 1 70 70 07 81

Belgium: +32 27 93 38 47

Germany: +49 69 22 22 26 25

Netherlands: +31 20 79 56 614

Switzerland: +41 44 58 07 145

United Kingdom: +44 207 19 28 338

United States: +1 646-741-3167

The presentation accompanying this conference call will be available on Inventiva's website in the "Investors" – "Financial Results & Presentations" section at the same time and can be followed live at: <https://edge.media-server.com/mmc/p/wo3raaz4>.

A replay of the conference call and the presentation will be available during 12 months after the event at: <https://inventivapharma.com/investors/financial-results-presentations/>.

### Next financial results publication

- **Revenues and cash position for the first quarter of 2022:** Monday, May 16, 2022 (after U.S. market close)

### About Inventiva

Inventiva is a clinical-stage biopharmaceutical company focused on the research and development of oral small molecule therapies for the treatment of NASH and other diseases with significant unmet medical need. The Company benefits from a strong expertise and experience in the domain of compounds targeting nuclear receptors, transcription factors and epigenetic modulation. Inventiva's lead product candidate, lanifibranor, is currently in a pivotal Phase III clinical trial, NATiV3, for the treatment of adult patients with NASH, a common and progressive chronic liver disease for which there are currently no approved therapies.

The Company has established a strategic collaboration with AbbVie in the area of autoimmune diseases that resulted in the discovery of the drug candidate cedirogant (ABBV-157), an oral ROR $\gamma$  inverse agonist which is being evaluated in a Phase IIb clinical trial, led by AbbVie, in adult patients with moderate to severe chronic plaque psoriasis. Inventiva's pipeline also includes odiparcil, a drug candidate for the treatment of adult mucopolysaccharidoses (MPS) VI patients. As part of Inventiva's decision to focus clinical efforts on the development of lanifibranor, it suspended clinical efforts relating to odiparcil and is reviewing available options with respect to its potential further development. Inventiva is in the process of selecting an oncology development candidate for its Hippo signalling pathway program.

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, and clinical development. It 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](http://www.inventivapharma.com).

### Contacts

#### **Inventiva**

Pascaline Clerc  
VP of Global External Affairs  
[media@inventivapharma.com](mailto:media@inventivapharma.com)  
+1 240 620 9175

#### **Brunswick Group**

Laurence Frost /  
Tristan Roquet Montegon /  
Aude Lepreux  
Media relations  
[inventiva@brunswickgroup.com](mailto:inventiva@brunswickgroup.com)  
+33 1 53 96 83 83

#### **Westwicke, an ICR Company**

Patricia L. Bank  
Investor relations  
[patti.bank@westwicke.com](mailto:patti.bank@westwicke.com)  
+1 415 513 1284

### Important Notice

*This press release contains “forward-looking statements” within the meaning of the safe harbor provisions of the Private Securities Litigation Reform Act of 1995. All statements, other than statements of historical facts, included in this press release are forward-looking statements. These statements include, but are not limited to, forecasts and estimates with respect to Inventiva’s pre-clinical programs and clinical trials, clinical trial data releases, pipeline and preclinical and clinical development plans, anticipated milestones, milestone payments, royalties and product sales, future activities, expectations, plans and prospects of Inventiva, the sufficiency of Inventiva’s cash resources and expectations with respect to the potential commercial success and potential revenues of Inventiva’s product candidates. 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”, “would”, “could”, “might”, “should”, 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 guarantees 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, that product candidates will receive the necessary regulatory approvals, or that any of the anticipated milestones by Inventiva or its partners will be reached on their expected timeline, or at all. 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 is a clinical-stage company with no approved products and no historical product revenues, 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 adverse drug reactions 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, and preclinical studies and clinical development programs and timelines, its financial condition and results of operations could be materially and adversely affected by the COVID-19 pandemic and geopolitical events, such as the conflict between Russia and Ukraine, which could delay the initiation, enrollment*

*and completion of Inventiva's clinical trials on anticipated timelines or at all. 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 for the year ended December 31, 2020 filed with the Autorité des Marchés Financiers on March 15, 2021, the Annual Report on Form 20-F for the year ended December 31, 2020 filed with the Securities and Exchange Commission on March 15, 2021 as well as the half-year financial report for the six months ended June 30, 2021 for additional information in relation to such factors, risks and uncertainties, in addition to the Universal Registration Document for the year ended December 31, 2021 expected to be filed with the Autorité des Marchés Financiers on March 16, 2021 and the Annual Report on Form 20-F for the year ended December 31, 2021 expected to be filed with the Securities and Exchange Commission on March 16, 2021.*

*All information in this press release is as of the date of the release. 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.*