

# Inventiva reports 2022 First Quarter Financial Information<sup>1</sup> and provides clinical development update

- Cash position<sup>2</sup> at €80.5m as of March 31, 2022
- The Group did not generate any revenue in Q1 2022
- Signature of a €50 million bullet credit facility agreement with the European Investment Bank
- Update on lanifibranor recruitment timing for Phase III trial in patients with NASH, as well as for the two Phase II trials in patients with NAFLD and type 2 diabetes, and in combination with empagliflozine

Daix (France), Long Island City (New York, United States), May 16, 2022 – Inventiva (Euronext Paris and Nasdaq: IVA) (the "Company"), a clinical-stage biopharmaceutical company focused on the development of oral small molecule therapies for the treatment of patients with non-alcoholic steatohepatitis (NASH) and other diseases with significant unmet medical needs, today reported its cash position as of March 31, 2022 and its revenues for the first quarter of 2022, and provided an update on its clinical programs.

#### **Cash Position**

As of March 31, 2022, Inventiva's **cash position** stood at €80.5 million compared to €95.4 million as of December 31, 2021.

Net cash used in operating activities amounted to €15.0 million in the first quarter of 2022 compared to €7.8 million for the same period in 2021. R&D expenses for the first quarter, mainly driven by the development of lanifibranor in NASH, were up 74% compared to the first quarter of 2022. This significant increase in R&D expenses is driven by the costs associated with the NATiV3 Phase III clinical trial with lanifibranor in NASH. Furthermore, the Company has received in January 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 adult patients with moderate to severe chronic plaque psoriasis.

Net cash used in investing activities for the first quarter of 2022 amounted to €0.1 million, compared to €1.1 million in the first quarter of 2021.

**No net cash from financing activities** was generated over the first quarter of 2022, same as for the first quarter of 2021.

Over the first quarter of 2022, the Company recorded a positive exchange rate effect on cash and cash equivalents of €0.2 million versus €3.5 million for the first quarter of 2021, due to the evolution of USD versus Euro.

 $<sup>^{\</sup>mathrm{1}}$  Non-audited financial information.

<sup>&</sup>lt;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 March 31, 2022, but are considered by the Company as liquid and easily available.



Considering its current R&D and clinical development programs and excluding any potential additional financial resources, the Company confirms that its cash, cash equivalents and short-term deposits should allow the Company to fund its operations through the end of the first quarter of 2023.

# **Revenues**

The Group did not generate any revenue in the first quarter of 2022, compared to a revenue of 0.1 million euros in the first quarter of 2021.

# Financial information after closing of the accounts

On May 16, 2022, Inventiva announced the signature of a €50 million bullet credit facility agreement with the European Investment Bank ("EIB") subject to certain conditions. The Company plans to use the facility toward its preclinical and clinical pipeline, including to help fund a portion of its Phase III clinical trial of lanifibranor in patients with NASH in order to seek accelerated approval in the US and conditional approval in the EU. This credit agreement is part of the EIB strategy to support biotech companies developing a high-level of expertise in various therapeutic areas with significant unmet medical needs.

# **Business update**

Recruitment for our pivotal Phase III trial NATiV3 of lanifibranor in NASH continues with full regulatory approval obtained in 23 out of 24 countries. Over 380 sites have been qualified and 193 activated in 18 countries. However, the COVID-19 pandemic and the conflict in Ukraine and related sanctions against Russia have impacted recruitment for NATiV3. Although the pandemic has eased globally, the strain on health systems continues to affect clinical sites, notably through staffing shortages and higher turnover. In addition, recruitment has been put on hold in Ukraine and the decision has been taken to remove all of Inventiva's planned sites in Russia from the trial.

The enrolment period of the Part 1 of the NATiV3 study was anticipated to last 12-month, however, as a result of the events mentioned above, we now expect to finalize part 1 recruitment for the NATiV3 study in the first half of 2023 versus the second half of 2022 as previously announced. Anticipated timing for data readouts for the Phase II trial of lanifibranor in NAFLD patients with type 2 diabetes (T2D) and for the Phase II LEGEND trial combining lanifibranor with SGLT2 inhibitor empagliflozine remain unchanged, with top-line results expected in the second half of 2022 and the second half of 2023 respectively.

Inventiva remains confident in the Company's recruitment strategy and has begun implementing measures to compensate for the loss of sites in Ukraine and Russia and provide additional support to clinical sites affected by the aftermath of the pandemic.

\*\*\*

#### **Anticipated potential next 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
- Publication of the results of the Phase II LEGEND 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
- Last Patient First Visit of the NATiV3 Phase III clinical trial evaluating lanifibranor in NASH now planned for first half of 2023



### **Upcoming investor conference participation**

- H.C. Wainwright Annual Global Life Sciences Conference, May 23-25, 2022
- Jefferies 2021 Healthcare Conference, June 8-10, 2022

# **Upcoming scientific conference participation**

- American Diabetes Association, 82<sup>nd</sup> Scientific Sessions, June 3-7, 2022
- International Liver Congress™ 2022, June 22–26, 2022

# **Next financial results publication**

Revenues and cash position for the first half of 2022: Thursday, July 28, 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 patients with NASH and other diseases with significant unmet medical needs. 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 its 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 80 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.

# **Contacts**

Inventiva

Pascaline Clerc VP of Global External Affairs media@inventivapharma.com +1 240 620 9175 Brunswick Group

Laurence Frost /
Tristan Roquet Montegon /
Aude Lepreux
Media relations
inventiva@brunswickgroup.com
+33 1 53 96 83 83

Westwicke, an ICR Company

Patricia L. Bank Investor relations 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, including recruitment for those trial, clinical trial data releases, including for part 1 of the Phase III clinical trial of lanifibranor in patients with NASH and two Phase II trials in patients with NAFLD and type 2 diabetes, and in combination with empagliflozine, pipeline and preclinical and clinical development plans, milestone payments, royalties and product sales, future activities, expectations, plans, growth and prospects of Inventiva and the sufficiency of Inventiva's cash resources and cash runway. 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", "plans", 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. Future 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, enrolment and retention of patients in clinical trials is an expensive and timeconsuming 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 current COVID-19 pandemic and geopolitical events, such as the conflict between Russia and Ukraine and related impacts and potential impacts on the initiation, enrolment and completion of Inventiva's clinical trials on anticipated timelines. 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, 2021 filed with the Autorité des Marchés Financiers on March 11, 2022 and the Annual Report on Form 20-F for the year ended December 31, 2021 filed with the Securities and Exchange Commission on March 11, 2022 for additional information in relation to such factors, risks and uncertainties.

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.