

Inventiva reports preliminary 2023 fiscal year financial information¹ and provides an update on its clinical trial NATiV3

- ▶ Revenues of €17.5 million for the full year of 2023, compared to €12.2 million for 2022
- ▶ Cash and cash equivalents at €26.9 million, short-term deposits at € 0.01 million², and long-term deposit at €9.0 million³ as of December 31, 2023, compared to €86.7 million, €1.0 million, and €0.7 million respectively, as of December 31, 2022
- ▶ Receipt on January 18, 2024 of the second tranche of €25 million under the EIB loan agreement⁴
- ▶ Estimated cash runway until the beginning of the third quarter of 2024⁵
- ▶ Patients currently enrolled in the Phase III NATiV3 trial are continuing treatment as Inventiva has voluntarily paused screening and randomization of new patients to implement additional screening eligibility criteria recommended by the independent Data Monitoring Committee following review of a reported treatment-related Suspected Unexpected Serious Adverse Reaction (SUSAR) of elevated aminotransferases in a patient enrolled in the trial
- ▶ This SUSAR is the first reported in all clinical trials with lanifibranor. Prior to this voluntary pause, Inventiva was on track to complete screening by the end of the first quarter of 2024; the Company anticipates that the pause of screening may extend the last patient first visit timeline to the first half of 2024

Daix (France), Long Island City (New York, United States), February 15, 2024 – 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 certain preliminary unaudited financial results as of and for the full year ended December 31, 2023, including cash, cash equivalents, and revenues, and provided an update on its clinical trial NATiV3.

¹ Unaudited

² Short-term deposits are included in the category “other current assets” in the IFRS consolidated statement of financial position as of December 31, 2023, and are considered by the Company as liquid and easily available.

³ The long-term deposit has a two-year term accessible prior to the expiration of the term with a notice period of 31 days and is considered as liquid by the Company

⁴ Inventiva-PR-EIB-Tranche-B-EN-01-10-2024.pdf (Inventivapharma.com)

⁵ 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. The Company may have based this estimate on assumptions that are incorrect and the Company may end up using its resources sooner than anticipated.

Frédéric Cren, Chairman, Chief Executive Officer and cofounder of Inventiva, stated: *“2023 has been an eventful year for the company. We achieved several key clinical milestones in our lanifibranor program, including a new partnership with Hepalys Pharma Inc. to develop and commercialize lanifibranor for the treatment of NASH in Japan and South Korea. During the year, we also raised approximately €36 million and received a \$10 million upfront payment under our agreement with Hepalys. This allowed us to draw down the second tranche of €25 million of the €50 million EIB loan in January 2024.*

We have advanced our pivotal NATiv3 Phase III clinical trial with lanifibranor in NASH after the implementation of the revised study design in early 2023, with 913 patients randomized to date. An adverse event of elevated aminotransferases has been reported in a patient enrolled in the trial following a scheduled visit. The patient has been asymptomatic and blood tests are improving. However, we have decided to temporarily suspend the screening and randomization of new patients to implement the exclusion criteria in line with the recommendations of the Data Monitoring Committee. All our teams are working diligently, and we are confident that recruitment will resume in around 4 to 6 weeks' time.”

Preliminary Unaudited Financial Results

As of December 31, 2023, the Company's **cash and cash equivalents** amounted to €26.9 million, short-term deposits to €0.01 million², and long-term deposit to €9.0 million³, compared to €86.7 million, €1.0 million, and €0.7 million as of December 31, 2022, respectively.

The decrease in cash and cash equivalents and short-term and long-term deposits between December 31, 2023, and December 31, 2022 was mainly caused by the increased use of cash in operating activities. This reflects the acceleration of clinical development activities in 2023, mostly driven by costs associated with the NATiv3 Phase III clinical trial of lanifibranor in NASH, and, to a lesser extent, with the LEGEND Phase IIa combination trial with lanifibranor and empagliflozin in patients with NASH and type 2 diabetes (“T2D”). This decrease is partially offset by:

- i) the financing of €35.7 million (gross amount) consisting of a reserved capital increase of €30.6 million and the issuance of royalty certificates of €5.1 million announced on August 31, 2023⁶,
- ii) the receipt of the \$10 million upfront payment from Hepalys Pharma, Inc. (“Hepalys”) on October 18, 2023, in accordance with the exclusive licensing agreement to develop and commercialize lanifibranor for the treatment of NASH and potentially other metabolic diseases in Japan and South Korea (the “Hepalys License Agreement”), and
- iii) the receipt of two short-term milestone payments, together amounting to a total of \$5 million, from Sino Biopharm, through its subsidiary Chia Tai Tianqing Pharmaceutical Group Co., Ltd. (“CTTQ”), following (a) receipt of the Investigational New Drug (“IND”) by the Chinese national Medical Products Administration (the “NMPA”) and (b) the enrollment by CTTQ of the first patient in China in the Company's ongoing pivotal NATiv3 Phase III clinical trial.

The above cash, cash equivalents and deposits do not include the disbursement of the second tranche of €25 million of the unsecured loan agreement executed with the European Investment Bank (“EIB”), which was received on January 18, 2024. Considering its current cost structure and forecasted expenditures, the Company estimates that, including the second tranche of the EIB loan, its cash, cash equivalents and deposits should allow the Company to fund its operations as currently planned until the beginning of the third quarter of 2024⁵.

Net cash used in operating activities amounted to (€81.6) million for the full year 2023, compared to (€44.9) million in 2022. R&D expenses for 2023 were up 82% compared to 2022. This increase was primarily due to the clinical development activities planned for and executed in 2023, partially offset by the upfront and milestone payments received from our partners, CTTQ and Hepalys (see above).

⁶ Inventiva-PR-Financing-operation-EN-08-31-2023-1.pdf (inventivapharma.com).

Net cash used in investing activities for the full year 2023 amounted to (€7.7) million, compared to €8.9 million generated for the same period in 2022. The change was mostly due to the variations in deposits between both periods.

Net cash generated from financing activities for the full year 2023 amounted to €29.1 million, compared to €37.3 million for 2022. The increase was mainly due to the financing of €35.7 million (gross amount) in August 2023, consisting of a capital increase and the issuance of royalty certificates.

The net cash generated from financing activities in 2022 was mainly driven by the equity sold through the Company's At-The-Market Program for approximately €9.4 million (gross proceeds) in June 2022, three loan agreements with a syndicate of French banks for a total amount of €5.3 million entered into in the first half of 2022, and the receipt of the first tranche of €25 million of the unsecured loan agreement with the EIB. In 2023 and 2022, the net cash generated (see above) is partially offset by the repayments of medical imaging equipment lease liabilities and loans.

In 2023, the Company recorded a **positive exchange rate effect** on cash and cash equivalents of €0.4 million, compared to a negative effect of (€1.0) million for the same period in 2022, due to the evolution of EUR/USD exchange rate.

Revenues

The Company's revenues for 2023 amounted to €17.5 million, compared to €12.2 million for the same period in 2022.

Revenues for 2023 consist mainly of i) €4.6 million, recognized under the license agreement with CTTQ following the receipt of two regulatory milestone payments from CTTQ in connection with IND approval from the NMPA to initiate the clinical development in mainland China of lanifibranor in NASH, and the randomization of the first patient and ii) €12.8 million, recognized under Hepalys License Agreement⁷.

Update on NATiV3 clinical trial with lanifibranor

Following a routine visit during the course of the NATiV3 trial, an adverse event of liver tests was reported in a patient enrolled in the trial. This event has been assessed as a treatment-related Suspected Unexpected Serious Adverse Reaction ("SUSAR"). The study drug was discontinued for that patient and liver tests which are being closely followed at the clinical site are improving and the patient has been without clinical symptoms throughout the period of observation. Additional lab tests and a liver biopsy performed after study drug discontinuation provided results compatible with autoimmune hepatitis. This patient presented at baseline in September 2022 with a histological diagnosis of NASH with stage 2 fibrosis. An earlier diagnostic analysis had raised a suspicion of autoimmune hepatitis dating back to June 2022.

The SUSAR was duly reported to all regulatory authorities and reviewed by the DMC in conjunction with other milder cases of elevation of aminotransferases among trial participants. The DMC subsequently recommended that the NATiV3 trial can continue with the following modifications:

- liver monitoring every 6 weeks for each patient; and
- amendment to the protocol to exclude newly screened patients diagnosed or with a predisposition to autoimmune liver or thyroid disease.

Following review of the data by the DMC, the Company made the decision to voluntarily pause screening and randomization to implement the DMC recommendations. Patients currently enrolled are continuing to receive treatment under the new liver monitoring schedule recommended by the DMC.

⁷ Inventiva-PR-PR-Japan-Licensing-Agreement-EN-09-20-2023-1.pdf (inventivapharma.com).

The Company is working diligently to make the appropriate amendments to the study protocol and the Informed Consent Form in line with the DMC recommendations and plans to resume screening and randomization in approximately four to six weeks once the operational implementation of the amendment is completed. Inventiva expects that the screening and randomization pause may extend the last patient first visit timeline for NATiV3 trial to the first half of 2024.

This SUSAR is the first reported in all clinical trials with lanifibranor. Prior to this voluntary pause, Inventiva was on track to complete screening by the end of the first quarter of 2024 with over 550 patients in screening and 913 patients randomized in the NATiV3 clinical trial, including 731 in the main cohort.

The pause in screening and randomization in NATiV3 is not impacting the publication of the topline results of the Phase IIa, LEGEND, evaluating lanifibranor in combination with empagliflozin and is expected for the first quarter of 2024.

Next key milestones expected

- Publication of the topline results of the LEGEND Phase IIa combination trial of lanifibranor in combination with empagliflozin in patients with NASH and T2D – *targeted for the first quarter of 2024*
- Last Patient First Visit of the NATiV3 Phase III clinical trial evaluating lanifibranor in NASH – *targeted for the first half of 2024*

Upcoming investor conference participation

- TD Cowen 44th Annual Health Care Conference – Boston, March 4-6, 2024

Upcoming scientific conference participation

- 16th Paris Hepatology Conference – Paris, March 18 -19, 2024
- 4th Annual Conference Liver Connect – Scottsdale, April 4-6, 2024

Next financial results publication

- **Financial results for the full fiscal year 2023:** Wednesday, March 27, 2024 (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, mucopolysaccharidoses (“MPS”) 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 is currently advancing one clinical candidate, has a pipeline of two preclinical programs and continues to explore other development opportunities to add to its pipeline.

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.

Inventiva's pipeline also includes odiparcil, a drug candidate for the treatment of adult 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 also in the process of selecting a candidate for its Hippo signaling pathway program.

The Company has a scientific team of approximately 90 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 B 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
EVP, Strategy and Corporate Affairs
media@inventivapharma.com
+1 202 499 8937

Brunswick Group

Tristan Roquet Montegon /
Aude Lepreux /
Julia Cailleteau
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, statements regarding preliminary unaudited financial results for Inventiva's fiscal year ended December 31, 2023, forecasts and estimates with respect to Inventiva's cash resources, forecasts and estimates with respect to Inventiva's pre-clinical programs and clinical trials, including design, duration, timing, recruitment costs, screening and enrolment for those trials, including the ongoing NATiV3 Phase III clinical trial with lanifibranor in patients with NASH and the LEGEND Phase IIa combination trial with lanifibranor and empagliflozin in patients with NASH, the impact of the SUSAR and the planned protocol amendment on clinical trials, including NATiV3 and LEGEND, and the results and timing thereof and regulatory matters with respect thereto, expectations with respect to patients in clinical trials, including the SUSAR patient, the potential for regulatory authorities to institute clinical holds and/or otherwise implement additional requirements and/or cause further delays in clinical trials, including in the NATiV3 and LEGEND trials, the potential development of and regulatory pathway for odiparcil, clinical trial data releases and publications, the information, insights and impacts that may be gathered from clinical trials, the potential therapeutic benefits of Inventiva's product candidates, including lanifibranor, potential regulatory submissions, approvals and commercialization, Inventiva's pipeline and preclinical and clinical development plans, future activities, expectations, plans, growth and prospects of Inventiva and its partners, 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", "designed", "hopefully", "target", "potential", "possible", "aim", 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. Future 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 the completion of financial closing procedures, final audit adjustments and other developments that may arise that could cause the preliminary financial results for 2023 to differ from the financial results that will be reflected in Inventiva's audited consolidated financial statements for the fiscal year ended December 31, 2023, that Inventiva cannot provide assurance on the duration of the pause in enrollment or the ultimate impact on the results or timing of the NATiV3 trial or regulatory matters with respect thereto, 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, in the absence of which, Inventiva may be required to significantly curtail, delay or discontinue one or more of its research or development programs or be unable to expand its operations or otherwise capitalize on its business opportunities and may be unable to continue as a going concern, 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 and its partners' clinical trials may not support Inventiva's and its partners' product candidate claims, Inventiva's expectations with respect to the impact of the SUSAR on its clinical trials may prove to be wrong and regulatory authorities may require additional holds and/or additional amendments to Inventiva's clinical trials, Inventiva's expectations with respect to the planned changes to the clinical development plan for lanifibranor for the treatment of NASH may not be realized and may not support the approval of a New Drug Application, Inventiva and its partners may encounter substantial delays beyond expectations in their clinical trials or fail to demonstrate safety and efficacy to the satisfaction of applicable regulatory authorities, the ability of Inventiva and its partners to recruit and retain patients in clinical studies, enrolment 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 and its partners' 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 and its partners' business, and preclinical studies and clinical development programs and timelines, its financial condition and results of operations could be materially and adversely affected by geopolitical events, such as the conflict between Russia and Ukraine and related sanctions, impacts and potential impacts on the initiation, enrolment and completion of Inventiva's and its partners' clinical trials on anticipated timelines and the state of war between Israel and Hamas and the related risk of a larger conflict, health epidemics, and macroeconomic conditions, including global inflation, rising interest rates, uncertain financial markets and disruptions in banking systems. 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, 2022 filed with the Autorité des Marchés Financiers on March 30, 2023 as amended on August 31, 2023, the Annual Report on Form 20-F for the year ended December 31, 2022 filed with the Securities and Exchange Commission (the "SEC") on March 30, 2023, and the Half-Year Report for the six months ended June 30, 2023 on Form 6-K filed with the SEC on October 3, 2023, for other risks and uncertainties affecting Inventiva, including those described from time to time under the caption "Risk Factors". Other risks and uncertainties of which Inventiva is not currently aware may also affect its forward-looking statements and may cause actual results and the timing of events to differ materially from those anticipated. 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 statement.

Inventiva has not completed the preparation of its consolidated financial statements for the year ended December 31, 2023. The preliminary unaudited financial results as of and for the year ended December 31, 2023 included in this press release are based on preliminary unaudited information and management's current expectations and estimates, are inherently uncertain and are subject to adjustment and revision in connection with Inventiva's financial closing procedures, Inventiva's completion of the preparation of the financial statements for its fiscal year ended December 31, 2023, any adjustments identified by Inventiva's auditors in the course of their review and audit, as applicable, of such financial statements, and other developments arising between now and the time such financial results are finalized. Inventiva's independent auditors have not audited, reviewed, examined, compiled, or performed any procedures with respect to these preliminary unaudited financial results nor have they expressed any opinion or any other form of assurance on these preliminary unaudited financial results. These preliminary unaudited financial results are not a comprehensive statement of Inventiva's financial results for these periods and should not be viewed as a substitute for full financial statements prepared in accordance with IFRS and are not necessarily indicative of Inventiva's results for any future period. Actual results and other disclosures may differ materially from these preliminary unaudited financial results.