

Inventiva Reports Preliminary 2023 First-Half Financial Information¹ and Business update

- Cash and cash equivalents at €31.2 million, short-term deposits at €0.05 million², and long-term deposit at €9.3 million³ as of June 30, 2023, compared to €86.7 million, €1.0 million and €0.7 million as of December 31, 2022, respectively
- Revenues of €1.9 m in H1 2023, compared to €0.1 million for the same period in 2022

Daix (France), Long Island City (New York, United States), July 27, 2023 – 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 financial results for the first half of 2023, including its cash, cash equivalents, and revenues, and provided a corporate update.

Preliminary Financial Results

As of June 30, 2023, the Company's **cash and cash equivalents** amounted to \leq 31.2 million, short-term deposits to 0.05 million², and long-term deposit to \leq 9.3 million³, compared to \leq 86.7 million, \leq 1.0 million and \leq 0.7 million as of December 31, 2022, respectively.

The €48.0 million decrease in cash and cash equivalents between June 30, 2023 and December 31, 2022 is mainly due to increased cash used in operating activities and reflects the 2023 planned acceleration of the clinical development activities 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").

Net cash used in operating activities amounted to (€45.2) million in the first half of 2023, compared to (€26.2) million for the same period in 2022. R&D expenses for the first half of 2023 were up 81 % compared to the first half of 2022. This increase is in line with the clinical development activities planned in 2023.

Net cash used in investing activities for the first half of 2023 amounted to (\in 7.7) million, compared to (\in 0.3) million in the first half of 2022. The change is mostly due to the change in deposits between both periods.

Net cash used in financing activities for the first half of 2023 amounted to (€2.2) million, compared to net cash provided by financing activities of €14 million in the first half of 2022. The net cash generated in financing activities in 2022 was mainly driven by the equity raised through the Company's At-The-Market Program for approximately €9.4 million (gross proceeds) in June 2022, and three loan agreements with a syndicate French banks for a total amount of €5.3 million entered into in the first half of 2022. In the first half of 2023, the net cash used in financing activities was mainly due to loan reimbursement and medical imaging equipment debt rents.

¹ Preliminary non-audited financial information.

² Short-term deposits are included in the category "other current assets" in the IFRS consolidated statement of financial position, 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.

Over the first half of 2023, the Company recorded a **negative exchange rate effect** on cash and cash equivalents of (≤ 0.4) million, compared to a positive effect of ≤ 2.4 million for the first half of 2022, due to the evolution of EUR/USD exchange rate.

Considering its current R&D and clinical development programs, the Company estimates that its existing cash, cash equivalents and deposits should allow the Company to **fund its operations until the end of the fourth quarter of 2023**⁴.

Revenues

The Company's revenues for the first half of 2023 amounted to €1.9 million, as compared to €0.1 million for the same period in 2022. The increase is mainly due to the receipt of the first regulatory milestone payment from CTTQ, Sino Biopharm's subsidiary, which was received in July 2023. The milestone payment was triggered in May 2023 after CTTQ received the Investigational New Drug ("IND") approval from the Chinese National Medical Products Administration ("NMPA") to initiate the clinical development in mainland China of lanifibranor in NASH.

Business updates

Inventiva announced positive topline results of the Phase II clinical trial conducted by Dr. Kenneth Cusi from the University of Florida, evaluating lanifibranor 800mg/daily in patients with NAFLD and T2D. Lanifibranor 800mg achieved the primary efficacy endpoint demonstrating a 44% reduction of hepatic fat measured by proton magnetic resonance spectroscopy following 24 weeks of treatment in patients with non-alcoholic fatty liver disease (NAFLD). A significantly higher proportion of patients achieved a greater than 30% liver triglyceride reduction as well as NAFLD resolution with lanifibranor compared to placebo. Lanifibranor treatment significantly improved both hepatic and peripheral insulin sensitivity, which translated into better glycemic control. The study met multiple secondary metabolic endpoints confirming the cardiometabolic benefit of lanifibranor in patients with NAFLD, and ability to improve adipose tissue function. The study confirmed the favorable safety and tolerability profile of lanifibranor.

Recruitment for our pivotal Phase III trial NATiV3 of lanifibranor in non-cirrhotic NASH continues with 389 sites activated in 23 countries, as of July 27, 2023. The previously announced revised study design which limits the duration of the trial to 120 weeks instead of up to 7 years, reduces the number of biopsies from three to two, and includes a 48-week active treatment extension study, has been approved in 16 countries and approximately 70% of activated sites are currently operating under the revised design. This new patient friendly design is improving the patient enrollment rate which has doubled since implementation in sites where the revised design has been in place for more than 3 months. In addition, the screen failure rate has been improving since September 2022. In China, our partner CTTQ, after receiving the IND approval from the NMPA on May 22 2023, has opted to join NATiV3 and we are actively working with our partner to activate 50 sites in mainland China and 2 sites in Hong Kong.

⁴ 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. This estimate does not take into consideration the €25 million second tranche of the loan agreement from the EIB, which is subject to certain conditions. The disbursement of the second tranche of €25 million is subject to, among other conditions, (i) the Company issuing warrants to EIB in accordance with the terms and conditions of the warrants agreements entered into July 1, 2022, (ii) the full drawdown of the first tranche, (iii) the receipt by the Company from the date of the EIB credit facility of an aggregate amount of at least €70.0 million (inclusive of the €18.0 million that was a condition for the disbursement of the first tranche), paid either in exchange for Company shares, or through upfront or milestone payments, (iv) an out-licensing, partnership or royalty transaction with an upfront payment of at least €10.0 million (condition that has been met with the signature of the licensing agreement of lanifibranor with Sino Biopharm/CTTQ); and (v) operational criteria based on patient enrollment and number of sites activated in the Company's NATiV3 Phase III clinical trial of lanifibranor in patients with NASH.



As of July 27, 2023, the percentage of patients randomized and those having successfully met all recruitment criteria, is approximately of 50% of the planned enrollment in NATiV3 and we are targeting the last patient first visit by the end of the second half of 2023.

Two Data and Safety Monitoring Board ("DSMB") meetings have taken place, both with recommendations to continue the study without any modification to the protocol. Of note the safety profile is consistent with what was observed in previous clinical trials with lanifibranor.

The baseline characteristics of the patients enrolled so far are aligned with expectations and the baseline characteristics of patients enrolled in the NATIVE Phase IIb trial. The main difference is a higher percentage of patients with T2D thus far in NATIV3 compared to NATIVE Phase IIb (58% vs 42% respectively). The effect size of lanifibranor therapy over_placebo in the Phase IIb clinical trial on the composite endpoint 'NASH resolution and fibrosis improvement', which corresponds to the primary efficacy endpoint in the Phase III NATIV3 clinical trial, was higher in patients with T2D versus patients who did not have diabetes: 21% and 26% for lanifibranor 800 and 1200 mg/day, respectively, in patients with T2D versus 7% and 22%, respectively, in patients who did not have diabetes⁵.

We are also continuing recruitment in the Phase II proof of concept clinical trial LEGEND, evaluating lanifibranor in combination with empagliflozin in patients with NASH and T2D. Recruitment of patients has been slower than expected and topline results are now targeted for the end of the first quarter of 2024 compared to the second half of 2023 as previously announced.

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 end of the first quarter of 2024
- Last Patient First Visit of the NATiV3 Phase III clinical trial evaluating lanifibranor in NASH targeted by the end of the second half of 2023

Upcoming investor conference participation

- H.C. Wainwright 25th Annual Global Investment Conference New York, September 11-13
- Lyon Pôle Bourse Lyon September 27th
- Stifel 2023 Healthcare Conference New York, November 14-15

Upcoming scientific conference participation

- XXVIII ALEH Congress (Asociación Latinoamericana para el Estudio del Hígado) Bogota, Colombia August 29th-September 1st
- Paris NASH meeting Paris September 7-9
- AASLD The Liver Meeting Boston November 10-14

Next financial results publication

Financial results for the first nine months of 2023: Thursday, September 28, 2023 (after U.S. market close)

⁵Efficacy of the panPPAR agonist lanifibranor on the histological endpoints NASH resolution fibrosis regression is similar in type-2 diabetic and nondiabetic patients: additional results of the NATIVE Phase 2b trial in non-cirrhotic NASH - Poster AASLD diabetes 2020 Final (inventivapharma.com)



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 an oncology development 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). <u>www.inventivapharma.com</u>

Contacts

Inventiva Pascaline Clerc VP of Global External Affairs media@inventivapharma.com +1 240 620 9175 Brunswick Group Tristan Roquet Montegon / Aude Lepreux / Matthieu Benoist 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 preliminary unaudited financial results for Inventiva's half-year ended June 30, 2023, forecasts and estimates with respect to Inventiva's pre-clinical programs and clinical trials, including design, duration, timing, recruitment costs, screening and enrollment for those trials, including the ongoing NATiV3 Phase III clinical trial with lanifibranor in NASH and the LEGEND Phase IIa combination trial with lanifibranor and empagliflozin in patients with NASH and type 2 diabetes, 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, and safety profile of Inventiva's product candidates, including lanifibranor, potential

PRESS RELEASE



regulatory submissions and approvals, and Inventiva's pipeline and preclinical and clinical development plans, future activities, expectations, plans, growth and prospects of Inventiva, the potential receipt of the second tranche under the EIB loan and any potential transaction or receipt of additional funds, future access to the two year short term deposit, and the sufficiency of Inventiva's cash resources and estimated 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", "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. 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 the completion of financial closing procedures, final adjustments and other developments that may arise that could cause the preliminary financial results for first half of 2023 to differ from the financial results that will be reflected in Inventiva's financial statements for the half-year ended June 30, 2023, 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 clinical trials may not support Inventiva's product candidate claims, Inventiva's expectations with respect to the 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 may encounter substantial delays in its clinical trials or Inventiva may fail to demonstrate safety and efficacy to the satisfaction of applicable regulatory authorities, the ability of Inventiva to recruit and retain patients in clinical studies, 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 geopolitical events, such as the conflict between Russia and Ukraine, related sanctions and related impacts and potential impacts on the initiation, enrollment and completion of Inventiva's clinical trials on anticipated timelines, 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 forwardlooking 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, and the Annual Report on Form 20-F for the year ended December 31, 2022 filed with the Securities and Exchange Commission on March 30, 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 statements.