

# Inventiva reports its 2024 full year results and provides a business update

- Revenues of €9.2 million for the full year of 2024
- Cash and cash equivalents at €96.6 million as of December 31, 2024
- ► First tranche of up to €348 million Structured Financing closed with aggregate gross proceeds of €116 million
- ► Last patient screened in the NATiV3 Phase 3 clinical trial of lanifibranor in MASH early in January 2025
- ▶ Pipeline prioritization plan presented to the workers council to focus exclusively on the development of lanifibranor, stopping all preclinical research activities and reducing the workforce by 50%

Daix (France), New York City (New York, United States), March 26, 2025 – 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 metabolic dysfunction-associated steatohepatitis ("MASH"), and other diseases with significant unmet medical needs, today reported its financial results for the full year ended December 31, 2024 and also provided a business update.

Frédéric Cren, CEO and cofounder of Inventiva, stated: "2024 was a pivotal year for Inventiva marked by significant progress in the NATiV3 Phase 3 trial evaluating lanifibranor for the treatment of MASH, for which we expect to complete enrollment shortly. We also published positive results from our LEGEND Phase 2 proof-of-concept study evaluating lanifibranor in combination with empagliflozin, which further elucidated the potential of lanifibranor as a treatment in patients with MASH and Type 2 diabetes who have a high risk of disease progression. On the financial front we secured a structured multi-tranche equity financing of up to €348 million, enabling us to move forward with our NATiV3 trial of lanifibranor."

## Key financial results for the full year of 2024

As of December 31, 2024, the Company's **cash and cash equivalents** amounted to €96.6 million compared to cash and cash equivalents at €26.9 million, short-term deposits at €0.01 million<sup>1</sup>, and long-term deposit at €9.0 million<sup>2</sup> as of December 31, 2023.

Net cash used in operating activities amounted to (€85.9) million in 2024, compared to (€81.6) million in 2023, an increase of 5.3%. R&D expenses, mainly driven by the development of lanifibranor in MASH, amounted to €90.9 million in 2024 and were down 17% compared to the €110.0 million in 2023. The decrease in R&D expenses over the period is primarily due to the temporary voluntary pause in the recruitment of patients in the NATiV3 Phase 3 clinical trial of lanifibranor in MASH following the Suspected Unexpected Serious Adverse Reaction

<sup>&</sup>lt;sup>1</sup> Short-term deposits were included in the category "other current assets" in the IFRS consolidated statement of financial position as of December 31, 2023, and were considered by the Company as liquid and easily available.

<sup>&</sup>lt;sup>2</sup> The long-term deposit had a two-year term accessible prior to the expiration of the term with a notice period of 31 days and was considered as liquid by the Company.



("SUSAR") reported in the first quarter of 2024 and, to a lesser extent, due to the completion of the LEGEND Phase 2 trial, a combination trial with lanifibranor and empagliflozin in patients with MASH and type 2 diabetes ("T2D"). For the second half of 2024, R&D expenses started to increase again following the restart of patient recruitment in NATiV3.

The operating cash flow for 2024 also includes the gross proceeds of \$10 million (net proceeds of €9.2 million), received as a milestone payment under the licensing agreement with Chia Tai Tianqing Pharmaceutical Group Co., Ltd. ("CTTQ"), as amended (the "CTTQ License Agreement"), in connection with the closing of the first tranche of the Structured Financing (as defined below) in October 2024, compared to an operating cash flow for 2023 that included i) €4.6 million, recognized under the CTTQ License Agreement and ii) €12.8 million, recognized under our exclusive licensing agreement with Hepalys Pharma, Inc. ("Hepalys"), (see also Revenues below).

Net cash generated / used from investing activities amounted to €8.7 million in 2024, compared to (€7.7) million in 2023. The change is mostly due to the variation in term deposits between both periods.

Net cash generated from financing activities for 2024 amounted to €145.6 million, compared to €29.1 million in 2023. The change is due to the receipt of:

- (i) the second tranche of €25 million drawn in January 2024 under the loan agreement granted by the European Investment Bank,
- (ii) aggregate proceeds of €20.1 million from the issuance of royalty certificates in July 2024³,
- (iii) aggregate gross proceeds of €94.1 million (net proceeds approximately €86.6 million) from the issuance of ordinary shares and prefunded warrants in October 2024 as part of the structured equity financing of up to €348 million announced on October 14, 2014<sup>4</sup> (the "Structured Financing"), and
- (iv) aggregate gross proceeds of €21.4 million (net proceeds approximately €20.1 million) from the issuance of ordinary shares and prefunded warrants in December 2024 as part of the Structured Financing

In 2024, the Company recorded €1.2 million positive exchange rate effect on cash and cash equivalents, compared to €0.4 million for the same period in 2023, due almost exclusively to the evolution of the EUR/USD exchange rate.

Considering its current cost structure and projected expenditure commitments, the Company estimates<sup>5</sup> that its cash and cash equivalents would enable it to finance its activities until the middle of the third quarter of 2025. Accordingly, the Company does not have sufficient net working capital to cover its operating needs for at least 12 months from the date of this press release.

Subject to the satisfaction of the applicable conditions precedent for the second tranche of the Structured Financing, the Company expects to receive in the second quarter of 2025 (i) gross proceeds of approximately €116 million from the second tranche of the Structured Financing and (ii) a second milestone payment of \$10 million from CTTQ under the CTTQ License Agreement. Taking into account its current cost structure and expected expenses, including the pipeline prioritization plan described below, the Company estimates<sup>5</sup> that its existing cash position and these expected potential additional sources of funding would enable it to finance its activities until the end of the third quarter of 2026.

<sup>&</sup>lt;sup>3</sup> Press release of July 18, 2024

<sup>&</sup>lt;sup>4</sup> Press release dated October 14, 2024

<sup>&</sup>lt;sup>5</sup> This estimate is based on the Company's current business plan for lanifibranor and excludes potential proceeds from subsequent tranches of the Structured Financing, any potential milestones payable to or by the Company and any additional expenditures related to other product candidates 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.



There can be no guarantee that the conditions precedent for this second tranche of the Structured Financing and the second milestone from CTTQ will be satisfied on their expected timing or at all.

The audit procedures on the consolidated financial statements have been carried out. The statutory audit report will include a section on the material uncertainty related to going concern and will be issued after verification of the management report. The Company's Board of Directors met on March 24, 2025 and approved the consolidated financial statements for the year ended December 31, 2024.

**Revenues** for 2024 consist mainly of the \$10 million (net proceeds of €9.2 million) milestone payment received from CTTQ, recognized under the CTTQ License Agreement following the receipt of the payment connection with the closing of the first part of the first tranche of the Structured Financing in October 2024, compared to €17.5 million for the same period in 2023.

Other income amounted to €5.5 million for the full year 2024, as compared to €5.7 million for 2023. Other income mainly consisted of French research tax credit (*credit d'impôt recherche*) for 2024 and 2023 in the amounts of €4.9 million and €5.3 million recorded in 2024 and 2023 respectively.

**R&D** expenses for the fiscal year ended December 31, 2024, amounted to (€90.9) million compared to (€110.0) million in 2023. As indicated above, this 17% decrease is primarily due to the temporary voluntary pause in the recruitment of patients in the NATiV3 trial following the SUSAR reported in the first quarter of 2024 and, to a lesser extent, due to the completion of the LEGEND trial. For the second half of 2024, R&D expenses started to increase again following the restart of patient recruitment in NATiV3.

Marketing and business development expenses was (€2.0) million for the fiscal year ended December 31, 2024, stable versus 2023.

**General and administrative expenses (G&A)** amounted to (€15.8) million for the fiscal year ended December 31, 2024, an increase of 14% compared to (€13.8) million in 2023, mainly due to increased personnel costs, including non-cash share-based payment expenses and other legal and compliance fees.

Net financial loss was (€86.0) million for the fiscal year ended December 31, 2024, compared to (€5.1) million in 2023. The net financial loss in 2024 is mainly due to (i) (€73.4) million non-cash IFRS treatment of the accounting at the fair value of derivative instruments in connection with the second tranche of the Structured Financing and ii) (€12.2) million, mainly non-cash, in loans and royalty certificates interests expenses.

Share of net loss – Equity method was ( $\leq$ 0.3) million for the fiscal year ended December 31, 2024, compared to ( $\leq$ 2.0) million for the same period in 2023, mainly due to the first equity method consolidation of Hepalys in Inventiva financial statements in 2023

**Income tax** amounted to (€0.3) million for the 2024 fiscal year, compared to (€0.6) million for 2023. This represents a regular partial non-cash write-off of the U.S. R&D tax credit deferred tax asset.

The Company's **net loss** for the full year 2024 was (€184.2), compared to (€110.4) million for 2023.

The following table presents Inventiva's income statement, prepared in accordance with IFRS, for the 2024 financial year, with comparatives for the 2023 financial year.



	Year ended	
(in thousands of euros)	December 31, 2024	December 31, 2023
Revenues	9,198	17,477
Other income	5,526	5,686
Research and development expenses	(90,880)	(110,012)
Marketing – business development expenses	(1,953)	(1,980)
General and administrative expenses	(15,839)	(13,837)
Other operating income (expenses)	(3,609)	(44)
Net operating loss	(97,558)	(102,709)
Net financial loss	(86,029)	(5,095)
Share of net loss - Equity method	(313)	(2 015)
Income tax	(313)	(607)
Net loss for the period	(184,212)	(110,426)
Basic/diluted loss per share (euros/share)	(3.08)	(2.43)
Weighted average number of outstanding shares used for computing basic/diluted loss per share	59,778,701	45,351,799

# Main areas of progress in the R&D portfolio

## **Lanifibranor in MASH**

- Publication in the peer-reviewed scientific journal Nature Communications of additional results from NATIVE
  Phase 2b clinical trial demonstrating improvement of markers of cardiometabolic health in patients with
  MASH treated with lanifibranor May 2024
- Positive recommendation from the fourth and the fifth scheduled meeting of DMC to continue the NATiV3 Phase 3 trial evaluating lanifibranor in patients with MASH without modification to the trial protocol – May and October 2024
- Approval of a new patent application in Japan, protecting the use of lanifibranor for the treatment of patients with cirrhosis. This new patent will be valid until November 8, 2039, excluding any potential patent term adjustments or extensions that may provide additional protection July 2024

## LEGEND study with lanifibranor with empagliflozin in patients with MASH and T2D

Positive results of Inventiva's interim analysis of the Phase 2 Proof-of-Concept clinical trial, LEGEND, evaluating lanifibranor in combination with empagliflozin in patients with MASH and poorly controlled T2D. LEGEND achieved its primary efficacy endpoint, demonstrated a statistically significant reduction in hepatic steatosis, as well as a statistically significant effect on several secondary and exploratory endpoints – March 2024

#### Other milestones

- Appointment of Andre Turenne as a member of the Board of Directors June 2024
- Appointments of Mark Pruzanski, M.D. as Chairman of the Board and Srinivas Akkaraju, M.D. as a member of the Board of Directors – December 2024



#### Post-2024 events

## Strategic pipeline prioritization plan

In February 2025, the Company informed the representatives of its Worker's Council of its plan to focus exclusively on the development of lanifibranor. The plan includes stopping all preclinical research activities except those required to support the lanifibranor program, together with strengthening the development team to prepare for potential filings for marketing approval and subsequent commercialization of lanifibranor for patients with MASH. The plan presented includes reducing the Company's current workforce by approximately 50%. Subject to ongoing negotiations with the Worker's Council, the plan is expected to be implemented during the second quarter of 2025 and all work on the Company's preclinical programs (YAP-TEAD and NR4A1) will be terminated.

#### NATiV3

- In January2025, screening of patients in the ongoing NATiV3 trial was completed. Completion of enrollment is expected within the first half of 2025 as previously communicated.
- In February 2025, following the review of the safety data of more than 1200 patients randomized in NATiV3 by the Data Monitoring Committee ("DMC"), Inventiva received a positive recommendation from the sixth scheduled meeting of DMC to continue the NATiV3 clinical trial without modification to the protocol.

#### Dissemination of preclinical and clinical results with lanifibranor

- In January 2025, the results of LEGEND evaluating lanifibranor in combination with empagliflozin in MASH were presented in an oral plenary presentation by Dr. Onno Holleboom at the Steatotic Liver Disease (SLD) Summit 2025 hosted by the European Association for the Study of the Liver (EASL).
- In January 2025, the results of the investigator-initiated clinical study led by Dr. Kenneth Cusi evaluating lanifibranor in patients with T2D and Metabolic dysfunction Associated Liver Disease ("MASLD") were published in *Journal of Hepatology*. The clinical trial demonstrated significant improvement of hepatic, muscle and adipose tissue insulin resistance in patients with MASLD and T2D treated with lanifibranor.
- In February 2025, the results from a preclinical study showing improvement of portal hypertension with lanifibranor treatment were published in Biomedicine & Pharmacotherapy.

## Initiation of the clinical development program of lanifibranor in Japan

In February 2025, Inventiva and Hepalys announced the initiation of the clinical development program of lanifibranor in Japan with the first dosing of the first participant in a Phase 1 clinical trial in Japan in patients and healthy volunteers evaluating the safety, tolerability, pharmacokinetics and pharmacodynamics of lanifibranor.

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## **Upcoming key milestones**

- Randomization of the last patient of the NATiV3 Phase 3 clinical trial expected in the first half of 2025
- Topline results of NATiV3 expected in the second half of 2026

# **Upcoming investor conference participation**

- Van Lanschot Kempen Life Sciences Conference, Amsterdam, April 2-3
- Jefferies Global Healthcare Conference, New York, June 3-5
- UBS Spring Biotech Conference, New York, June 24
- 8<sup>th</sup> Edition of Forum Lyon Pôle Bourse, Lyon, September 23



# **Upcoming scientific conference participation**

EASL Congress, Amsterdam, May 7-10

## **Conference call**

A conference call in English will be held tomorrow, Thursday, March 27, 2025, at 8:00 am (New York)/1:00 pm (Paris) to discuss 2024 financial results and business updates.

The conference call and the slides of the presentation will be webcast live at the following link: https://edge.media-server.com/mmc/p/vwusqh64

In order to receive the conference access information necessary to join the conference call, it is required to register in advance using the following link: https://register-conf.media-server.com/register/BI3038fbc689834ad6a437704e47ae8dcf. Participants will need to use the conference access information provided in the e-mail received at the point of registering (dial-in number and access code).

A replay of the conference call and the presentation will be available after the event one the Company's <u>website</u>.

# **Next financial results publication**

 Revenues and cash, cash equivalents and deposits for the first quarter of 2025: Friday, May 23, 2025 (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 MASH and other diseases with significant unmet medical need. The Company is currently evaluating lanifibranor, a novel pan-PPAR agonist, in the NATiV3 pivotal Phase 3 clinical trial for the treatment of adult patients with MASH, a common and progressive chronic liver disease.

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

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# **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 cash resources and expenses, the anticipated proceeds from the second tranche of the Structured Financing, the satisfaction in part or full of the conditions precedent to closing of the second tranche of the Structured Financing and the timing thereof, Inventiva's expectations regarding the CTTQ License Agreement, including the achievement of specified milestones thereunder and the timing thereof, the potential benefits of Inventiva's new governance, the timeline and potential benefit of the pipeline prioritization plan and related workforce reduction, forecasts and estimates with respect to Inventiva's NATiV3 Phase 3 clinical trial with lanifibranor in patients with MASH, including design, duration, timing, recruitment costs, screening, enrolment and randomization, funding, the impact of the SUSAR on the result and timing thereof and regulatory matters with respect thereto, clinical trial data releases and publications, the information, insights and impacts that may be gathered from clinical trials, the potential therapeutic benefits of lanifibranor, potential regulatory submissions, approvals and commercialization, Inventiva's pipeline and development plans, future activities, expectations, plans, growth and prospects of Inventiva and its partners, including CTTQ and Hepalys, and the potential commercialization of lanifibranor and achievement of any sales related thereto. 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 forwardlooking 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 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 that Inventiva cannot provide assurance on the ultimate impact on the results or timing of the NATiV3 trial or regulatory matters with respect thereto, that Inventiva is a clinicalstage 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 ability to obtain financing, to enter into potential transactions and Inventiva's ability to satisfy in part or full the closing conditions for subsequent tranches of the Structured Financing on the expected timing or at all, and whether and to what extent the prefunded warrants issued in connection with the Structured Financing may be exercised and by which holders, Inventiva's future success is dependent on the successful clinical development, regulatory approval and subsequent commercialization of its product candidate lanifibranor, 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 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 clinical development plan for lanifibranor for the treatment of MASH 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 business, preclinical studies and clinical development programs, including their 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, and the conflict in the Middle East and the related risk of a larger conflict, health epidemics, and macroeconomic conditions, including global inflation, fluctuations in 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, 2023 filed with the Autorité des Marchés Financiers on April 3, 2024 as amended on October 14, 2024 and the Annual Report on Form 20-F for the year ended December 31, 2023 filed with the Securities and Exchange Commission (the "SEC") on April 3, 2024 and the Half-Year Report for the six months ended June 30, 2024 on Form 6-K filed with the SEC on October 15, 2024 for other risks and uncertainties affecting Inventiva, including those described under the caption "Risk Factors", and in future filings with the SEC, including our Annual Report on Form 20-F for the year ended December 31, 2024 to be filed with the SEC. 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.