

# Inventiva provides a corporate update and reports its unaudited 2024 first-half financial results

- ▶ Recruitment in NATiV3 clinical trial progresses with over 85% of the targeted number of patients enrolled in the main cohort and a statistical powering of the study expected to be superior to 95% for both doses evaluated in the trial.
- ▶ Baseline characteristics of patients randomized in the main cohort of NATiV3 remain consistent with the characteristics of patients enrolled in the completed Phase IIb, NATIVE, clinical trial.
- ▶ Blinded analyses of patients in NATiV3 suggest a positive evolution of key biomarkers comparable to the Phase IIb, NATIVE, study results and that weight gain plateaus and stabilizes starting at week 24 to 36.
- ► Last patient randomization is anticipated in the first half of 2025 following the end of screening planned for the end of the year as guided. Topline results are expected in the second half of 2026.
- Cash and cash equivalents at €10.1 million as of June 30, 2024, compared to cash and cash equivalents at €26.9 million, €0.01¹ million of short-term deposits and €9.0² million of long-term deposits as of December 31, 2023.
- ► Inventiva is actively reviewing potential financing and discussing strategic options with its financial advisors and potential counterparties, including its major shareholders and potential new investors.
- On July 18, 2024, Inventiva issued royalty certificates subscribed by Samsara BioCapital and existing shareholders (BVF Partners, NEA, Sofinnova and Yiheng) for an amount of €20.1 million.
- ➤ Cash runway extended until mid-October 2024³, following the issuance of the royalty certificates announced on July 18, 2024, and the implementation of cash preservation measures.

<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 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, were accessible prior to the expiration of the term with a notice period of 31 days and were considered as liquid by the Company.

<sup>&</sup>lt;sup>3</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. The Company may have based this estimate on assumptions that are incorrect, and the Company may end up using its resources sooner than anticipated.



Daix (France), Long Island City (New York, United States), September 25, 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 metabolic dysfunction-associated steatohepatitis ("MASH"), also known as non-alcoholic steatohepatitis ("NASH"), and other diseases with significant unmet medical needs, today provided a corporate and a financial update for the six months ended June 30, 2024.

"We are actively engaged in discussions seeking additional financing with the goal of funding the Company through the anticipated Phase III topline results. We believe the recent €20.1 million royalty deal, subscribed by Samsara BioCapital and longstanding shareholders such as BVF Partners, NEA, Sofinnova, and Yiheng, is a powerful endorsement of our strategy. Their continued support underscores their strong confidence in lanifibranor and our vision for transforming patient care. We remain confident in the ongoing progress of our Phase III NATiV3 clinical trial." stated Frédéric Cren, Chairman, Chief Executive Officer and cofounder of Inventiva. "We would like to thank our key partners and the clinical trial sites on the Phase III clinical trial for their continued efforts and engagement in our study which is reflected in the progress in the recruitment for NATiV3."

# Update on its clinical program evaluating lanifibranor for the treatment of MASH

As of the date hereof, the NATiV3 trial is progressing with screening at 359 sites across 24 countries. To date, 837 patients have been randomized in the main cohort, achieving more than 85% of the targeted enrolment. 296 patients have been randomized in the exploratory cohort, compared to the original target of 200 patients. The top 10 countries contributed for more than 90% of patients randomized, with the United States accounting for 61%.

The patients' characteristics at baseline in the main cohort align with expectations and are consistent with those from the NATIVE Phase IIb clinical trial ("NATIVE"). Furthermore, 13% of patients enrolled in the main cohort were on a stable dose of GLP-1 receptor agonist at baseline which should provide valuable insights into the potential benefits of a combination of this class of products with lanifibranor.

A power analysis of NATiV3 conducted in September 2024 which assumed a response rate on the primary endpoint based on the results from Phase IIb, NATIVE, using the same patient population randomized in NATiV3 and a dropout rate similar to the one observed in the ongoing NATiV3 trial, confirmed that the study is well powered with both doses expected to exceed 95% of statistical power. A blinded review which included 545 patients at week 24 and 119 patients at week 72 (placebo and treatment arms pooled) showed a positive evolution of hepatic, lipid, glycaemic and fibrosis markers as well as of scores using Fibroscan®, comparable to the NATIVE Phase IIb study results which suggests that lanifibranor is having the expected benefits in the patients enrolled in NATiV3. The blinded analysis also showed a similar weight gain as the one observed after six months in the NATIVE Phase IIb trial. Furthermore, in NATiV3 the weight gain appears to plateau and stabilize after 24 to 36 weeks of treatment. If confirmed, this encouraging result highlights the particular profile of lanifibranor versus single PPAR gamma in particular pioglitazone, where such a plateau effect has not been observed<sup>4</sup>.

<sup>4</sup>Sanyal A et al. NEJM, 362; 18, 2010



# Key financial results for the first half of 2024

(in thousands of euros)	Six months ended	
	June 30, 2024	June 30, 2023
Revenues	41	1,901
Other income	2,693	4,721
Research and development expenses	(46,822)	(54,062)
Marketing – business development expenses	(598)	(705)
General and administrative expenses	(7,701)	(6,812)
Other operating income (expenses)	138	(44)
Net operating loss	(52,249)	(55,003)
Net financial income	3,507	(273)
Share of net loss - Equity method	(168)	0
Income tax	(119)	7
Net loss for the period	(49,029)	(55,269)
Basic/diluted loss per share (euros/share)	(0.94)	(1.31)
Weighted average number of outstanding shares used for computing basic/diluted loss per share	51,982,093	42,044,796

The Company did not record any **revenues** in the first half of 2024, as compared to €1.9 million recorded during the same period in 2023. The revenues recorded by the Company in the first half of 2023 were attributed to a milestone payment by CTTQ, a Sino Biopharm subsidiary, after it received the Investigational New Drug ("IND") approval from the Chinese National Medical Products Administration ("NMPA") in May 2023, allowing the initiation of the clinical development of lanifibranor in MASH/NASH in mainland China.

**Other income** amounted to €2.7 million for the first half of 2024, as compared to €4.7 million for the first half of 2023, decreased 42.5% mainly driven by the reclassification in 2024 of some R&D expenses reinvoiced to CTTQ that were previously recorded in other income, and to a lesser extent by the slight decrease in research tax credit due to decrease in R&D expenses for the period compared to the first half of 2023.

**R&D** expenses for the first half of 2024 amounted to €46.8 million, mainly driven by the development of lanifibranor in MASH/NASH and were down 13.4% compared to the €54.1 million for the first half of 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 III clinical trial of lanifibranor in MASH/NASH ("NATiV3") following the Suspected Unexpected Serious Adverse Reaction ("SUSAR") previously reported in the first quarter of 2024 and, to a lesser extent, due to the completion of the LEGEND Phase IIa combination trial with lanifibranor and empagliflozin in patients with MASH/NASH and type 2 diabetes ("T2D"). R&D expenses are expected to increase in the second half of 2024 following the restart of patient recruitment in NATiV3, as well as the planned clinical development activities and related costs associated with the NATiV3 for the second half of 2024.

Marketing and business development expenses stood at €0.6million for the first half of 2024 compared to €0.7 million for the same period in 2023.

**General and administrative expenses (G&A)** amounted to €7.7 million in the first half of 2024, compared to €6.8 million in the first half of 2023. Increase by 13% is mainly due to personnel costs and consulting fees.

**Net financial income (loss)** amounted to €3.5 million in the first half of 2024, compared to (€0.3) million. The income mainly relates to the change in fair value of the warrants issued to the European Investment Bank ("EIB")



in connection with the drawdown of two tranches of €25 million under our unsecured loan agreement with EIB (the "Finance Contract"), and is partially offset by an increase in the financial interests borne on those tranches and on the royalty certificates issued in August 2023 (the "2023 Royalty Certificates").

The Company's **net loss** stood at (€49.0) million as of June 30, 2024, compared to (€55.3) million as of June 30, 2023.

As of June 30, 2024, the Company's **cash and cash equivalents** stood at €10.1 million, compared to cash and cash equivalents at €26.9 million, short-term deposits¹ of €0.01million, and long-term deposits² of €9.0 million as of December 31, 2023.

Net cash used in operating activities amounted to (€48.3) million in the first half of 2024, compared to (€45.2) million for the same period in 2023 down by 6.8% while the R&D expenses for the first half of 2024 were (€46.8) million, down 13.4% compared to the first half of 2023 (see above) partially offset by a negative working capital variance between both periods.

Net cash generated from investing activities for the first half of 2024 amounted to €8.9 million, compared to (€7.7) million used in the first half of 2023. The change is mostly due to the variation in term deposits between both periods.

Net cash generated from financing activities for the first half of 2024 amounted to €22.6 million, compared to (€2.2) million used in the first half of 2023. The change is due to the second tranche of €25 million drawn in January 2024 under the Finance Contract. As a condition to the drawdown of the second tranche, the Company issued 3,144,654 warrants to the EIB.

Over the first half of 2024, the Company recorded a **positive exchange rate effect** on cash and cash equivalents of  $\in 0.1$  million, compared to a negative effect of ( $\in 0.4$ ) million for the first half of 2023, due to the evolution of the EUR/USD exchange rate.

# Financial information after closing the accounts

On July 18, 2024, Inventiva announced the issuance of royalty certificates (the "2024 Royalty Certificates") subscribed by Samsara BioCapital, and existing shareholders BVF Partners, NEA, Sofinnova, and Yiheng, for an amount of €20.1 million. The 2024 Royalty Certificates give the holders thereof the right to an annual payment of royalties equal to 3% of the potential future net sales of lanifibranor, if any, in the United States, the European Union and the United Kingdom over a 14-year term from the date of their issuance<sup>5</sup>.

Considering its current cost structure and forecasted expenditures and including the proceeds of €20.1 million from the issuance of the 2024 Royalty Certificates and the implementation of cash preservation measures, the Company estimates that its cash, cash equivalents and deposits should allow the Company to fund its operations until mid-October 2024<sup>6</sup>. These factors raise substantial doubt regarding the Company's ability to continue as a going concern.

The Company is actively reviewing potential financing and discussing strategic options with its financial advisors and potential counterparties, including its major shareholders and potential new investors. In particular, the Company may seek to raise additional funds to achieve its development goals for its research and development programs through potential public or private equity or debt offerings and potential strategic transactions such as

<sup>&</sup>lt;sup>5</sup> Inventiva-PR-Royalty-Deal-EN-07-18-2024.pdf (inventivapharma.com)

<sup>&</sup>lt;sup>6</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. The Company may have based this estimate on assumptions that are incorrect, and the Company may end up using its resources sooner than anticipated.



business development partnerships, royalty and/or business combination transactions, and/or other arrangements or transactions or series of transactions or a combination thereof.

The review of potential financial and strategic options may not result in any particular action or transaction being pursued, entered into or consummated, and there is no assurance as to the timing, sequence or outcome of any action or transaction or series of actions or transactions.

The unaudited half-year condensed consolidated statement of the Company as at and for the six-month period ended June 30, 2024, have been prepared under the responsibility of the Board of Directors and approved by the latter based on the principle of continuity of operations on September 23, 2024, for the purposes of this press release.

To date, given the current context of the discussions conducted by the Company on the financing necessary to continue its activities mentioned above, the Statutory Auditors have not yet issued their report on the review of the condensed consolidated half-yearly financial statements. They have informed the Company that they are unable to conclude on the appropriateness of the Company's use of the going concern basis of accounting and on the relevance of the related information presented in these accounts prepared in accordance with this basis of accounting. Consequently, pending the outcome of these discussions, the Statutory Auditors are unable, to date, to form a conclusion on the condensed consolidated half-yearly financial statements.

The publication of the audited interim financial report including the half year financial statement for the period ended June 30, 2024, has therefore been delayed and will occur as soon as possible.

# Next key milestones expected<sup>7</sup>

- Randomization of the last Patient of the NATiV3 Phase III clinical trial evaluating lanifibranor in MASH/MASH
   expected in the first half 2025 following the end of screening targeted for the end of the year 2024.
- Topline results of NATiV3— expected in the second half of 2026.

### **Upcoming investor conference participation**

- KBC Securities life sciences conference September 26 Brussels
- H.C. Wainwright 9<sup>th</sup> Annual MASH Investor Conference October 7 Virtual
- Portzamparc BNP Paribas Séminaire Biotech & Santé October 8-9 Virtual
- Guggenheim Global Healthcare Conference November 11-13 Boston
- Stifel Healthcare Conference November 18-19 New York

# **Upcoming scientific conference participation**

AASLD The Liver Meeting – November 15-19 – San Diego, United States

#### **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/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 is currently advancing one clinical candidate and has a pipeline of two preclinical programs

<sup>&</sup>lt;sup>7</sup> Assuming the Company obtains necessary financing



Inventiva's lead product candidate, lanifibranor, is currently in a pivotal Phase III clinical trial, NATiV3, for the treatment of adult patients with MASH/NASH, a common and progressive chronic liver disease.

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

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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, preliminary unaudited financial information, expectations with respect to Inventiva's cash resources and estimated cash runway, including the effects thereon by cash preservation measures and Inventiva's ability to execute any potential financing or strategic options or further transactions or arrangements, including the impacts of any such transaction or arrangement, and the likelihood of success thereof, expectations with respect to the review of Inventiva's financial statements by its auditors and the publication thereof, 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 MASH/NASH, 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 alone and in combination with other treatments, potential regulatory submissions and approvals, and Inventiva's pipeline and preclinical and clinical development plans, future activities, expectations, plans, growth and prospects of Inventiva and its partners, business and regulatory strategy, the potential commercialization of lanifibranor and achievement of any sales related thereto, potential payment of royalties and anticipated future performance,. 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", "opportunity", "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 quarantees 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 the first half of 2024 to differ from the financial results that will be reflected in Inventiva's final financial statements, the outcome of the auditor's review of the Company's financial statements, including the use of the going concern basis of accounting and the information disclosed in the financial statements, that Inventiva cannot provide assurance on the impacts of the SUSAR on 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 ability to obtain financing and to enter into potential transactions or further arrangements with its creditors and the impacts therefrom, 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 its clinical trials may prove to be wrong and regulatory authorities may require holds and/or amendments to Inventiva's clinical trials, Inventiva's expectations with respect to the changes to the clinical development plan for lanifibranor for the treatment of MASH/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, 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 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, enrollment 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. The review of potential financial and strategic options may not result in any particular action or transaction being pursued, entered into or consummated, and there is no assurance as to the timing, sequence or outcome of any action or transaction or series of actions or transactions. If Inventiva is unable to continue as a going concern, it may have to liquidate its assets and may receive less than the value at which those assets are carried on its financial statements, and it is likely that investors will lose all or part of their investment. 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, 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 for other risks and



uncertainties affecting Inventiva, including those described under the caption "Risk Factors," and in our future filings 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.