

## Inventiva provides an update on its NATiV3 clinical program evaluating lanifibranor in patients with MASH/NASH and its financial position

- ▶ Recruitment in NATiV3 clinical trial continues in both cohorts with over 80% of the targeted number of patients enrolled in the main cohort and 100% in the exploratory cohort of NATiV3.
- ▶ Analysis of the baseline characteristics of all patients randomized in the main cohort of NATiV3 show a patient profile similar to patients randomized in the NATIVE Phase IIb clinical trial.
- ▶ A blinded analysis of all randomized patients suggests weight gain plateaus and stabilizes between week 24 and 36.
- ▶ First visit of the last patient of NATiV3 is anticipated to occur during the second half of 2024, and topline results are expected at the beginning of the second half of 2026.
- ▶ Patent portfolio strengthened with new patent secured protecting the compound until 2043.
- ▶ The Company is currently working on multiple fronts to secure financing to fund the continuity of its activities.

**Daix (France), Long Island City (New York, United States), July 5, 2024** – Inventiva (Euronext Paris and Nasdaq: IVA) (“**Inventiva**” or the “**Company**”), a clinical-stage biopharmaceutical company focused on the development of oral small molecule therapies for the treatment of patients with metabolic dysfunction-associated steatohepatitis (“**MASH**”), also known as non-alcoholic steatohepatitis (“**NASH**”), and other diseases with significant unmet medical needs, today provided an update on its clinical program evaluating lanifibranor for the treatment of MASH/NASH and its financial position.

**Frederic Cren, Chairman, Chief Executive Officer, and cofounder of Inventiva stated:** “*We have made good progress with the recruitment in our Phase III clinical trial and continue to see a strong engagement of clinical trial sites in NATiV3. We are encouraged by the patient characteristics we are seeing in the main cohort of NATiV3 compared to those of our Phase IIb trial and above all by the plateau effect we see in the weight gain curve which confirms the differentiated profile of our panPPAR compound versus single PPAR gamma compounds such as pioglitazone. The data obtained from our various clinical studies demonstrate that lanifibranor could fully address the broad spectrum of the disease and recent presented data at the EASL Liver Congress from other compounds in development further bolster our belief in the potential of oral lanifibranor for use alone or in combination therapy. We are continuing to evaluate financing options to extend our current cash runway and continue our activities as we are determined to bring lanifibranor to market as a treatment option for patients with MASH.*”

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

The recruitment in NATiV3 is advancing with screening ongoing at 347 sites across 19 countries. As of July 5, 2024, 1,027 patients have been randomized of which 784 patients in the main cohort of NATiV3, representing 82% of the targeted number. The geographical distribution of the main cohort confirms that North America and Western Europe are the key contributors to patient recruitment (67% and 21% respectively) while China has only contributed marginally (2% of patients). The targeted number of 200 patients to be recruited in the exploratory cohort has been met with 243 patients randomized to date. The recruitment in the exploratory will continue until recruitment is complete in the main cohort.

The Company estimates that, given the number of patients currently in screening who are eligible for enrolment in the main cohort, the Company must recruit an additional 165 patients. Due to a delay of approximately 3 to 5 months in recruitment, the Company is currently now targeting: the last patient first visit for the second half of 2024 and the publication of the topline results in the beginning of the second half of 2026.

The baseline characteristics of the patients enrolled so far in the main cohort are in line with the expectations of the Company and are consistent with those from the NATiVE Phase IIb clinical trial of lanifibranor in patients with MASH/NASH (“NATiVE”). In addition, 13% of patients enrolled in the main cohort were receiving a stable dose of GLP1 receptor agonist and 9% a stable dose of SGLT2 inhibitors at baseline and should provide the Company with insights on the potential of the benefits of a combination of these class of products with lanifibranor.

Importantly, a blinded review which included 780 patients enrolled in the main cohort of NATiV3 (placebo and treatment arms pooled) showed a similar weight gain as the one observed during the NATiVE Phase IIb trial which seems to plateau and stabilize after 24 to 36 weeks of treatment, and this even in the subgroup of patients who have gained more than 5% weight. 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>1</sup>.

### Intellectual property strategy

We continue to work to reinforce lanifibranor patent portfolio. As of today, lanifibranor patent portfolio is made up of 20 patent families comprising both patents and patent applications fully owned by Inventiva. These patent families are respectively directed to lanifibranor product, method of treatment, combination therapy, process, formulation and diagnostic methods. With our patent family directed to crystalline forms of lanifibranor (patent applications pending), the company expects to potentially extend protection on lanifibranor product until at least 2043.

### Financial update

Considering the Company’s cost structure and forecasted expenditures, and without taking into account additional cash preservation measures that the Company may implement in the short term, the Company estimates that its cash, cash equivalents and deposits will allow the Company to fund its operations as planned through the second half of July 2024<sup>2</sup>. The Company estimates that, as of May 31, 2024, the Company’s cash and cash equivalents were (non-audited) €9.6 million, short-term deposits were €0.1 million<sup>3</sup>, and long-term deposits

<sup>1</sup> Sanyal A et al. NEJM, 362 ; 18, 2010

<sup>2</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.

<sup>3</sup> Short-term deposits are classified as "other current assets" in the consolidated statement of financial position under IFRS and are considered by the Company to be liquid and readily available.

were €10.0 million<sup>4</sup>, compared with €26.9 million, €0.01 million and €9 million, respectively, as of December 31, 2023.

In order to finance its activities and advance its development objectives for its research and development programs, the Company will need to raise additional funds. To date, the Company has explored a variety of transactions, including the issuance of debt, equity and other instruments, which thus far have not been successful. However, the Company is working to complete a royalty-based financing that would extend its cash runway through the summer of 2024, which it anticipates announcing in the near-term. Even if the royalty-based financing is successful (of which there can be no assurance), the Company will need to raise additional funds, and it is continuing to actively evaluate potential financing (including debt, equity and equity-linked or other instruments) and strategic options.

### About lanifibranor

Lanifibranor, Inventiva's lead product candidate, is an orally-available small molecule that acts to induce antifibrotic, anti-inflammatory and beneficial vascular and metabolic changes in the body by activating all three peroxisome proliferator-activated receptor ("PPAR") isoforms, which are well-characterized nuclear receptor proteins that regulate gene expression. Lanifibranor is a PPAR agonist that is designed to target all three PPAR isoforms in a moderately potent manner, with a well-balanced activation of PPAR $\alpha$  and PPAR $\delta$ , and a partial activation of PPAR $\gamma$ . While there are other PPAR agonists that target only one or two PPAR isoforms for activation, lanifibranor is the only pan-PPAR agonist in clinical development for the treatment of MASH/NASH. Inventiva believes that lanifibranor's moderate and balanced pan-PPAR binding profile contributes to the favorable tolerability profile that has been observed in clinical trials and pre-clinical studies to date. The FDA has granted Breakthrough Therapy and Fast Track designation to lanifibranor for the treatment of MASH/NASH.

### About the NATiV3 Phase III trial

NATiV3 is a randomized, double-blind, placebo-controlled clinical trial designed to evaluate the long-term efficacy and safety of lanifibranor (800mg/daily and 1200mg/daily) in adult patients with biopsy-proven non-cirrhotic MASH/NASH and F2/F3 stage of liver fibrosis. The trial takes place in 24 countries and in more than 400 clinical sites and recruits approximately 900 patients to be treated over a 72-week period. The effect of lanifibranor will be assessed on several histological endpoints, including MASH/NASH resolution and improvement of fibrosis of at least one stage. An exploratory cohort is anticipated to enroll approximately 200 patients with MASH/NASH and fibrosis screen-failed on histology for the main NATiV3 clinical trial. Inventiva anticipates that this exploratory cohort may allow the generation of additional data using non-invasive tests and contribute to the regulatory safety database requirement to support the planned submission for potential accelerated approval to the Food and Drug Administration (FDA) and potential conditional approval to the European Medicines Agency (EMA) of lanifibranor for the treatment of MASH/NASH. Topline results of NATiV3 are expected for the second half 2026. For more information about NATiV3, visit [clinicaltrials.gov](https://clinicaltrials.gov).

### 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, has a pipeline of two preclinical programs and continues to explore other development opportunities to add to its pipeline.

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<sup>4</sup> The two-year long-term deposit can be accessed before expiry of the term with 31 days' notice and is considered liquid by the Company.



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](http://www.inventivapharma.com)

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*This press release contains certain "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 with respect to Inventiva's estimated cash position, including its estimated cash runway, Inventiva's review of potential financing and strategic options and their outcome and likelihood of success, the completion of a royalty-based financing that would extend its cash runway through the summer, the success of Inventiva's intellectual property strategy, as well as statements regarding Inventiva's clinical trial, including the design, duration, timing, recruitment, costs, screening and enrollment for those trials, including the ongoing NATiV3 Phase III clinical trial with lanifibranor in MASH/NASH, 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, business and regulatory strategy, the anticipated timing of Inventiva's Phase III clinical trial of lanifibranor, the commercialization of lanifibranor and achievement of any sales related thereto, 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 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 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, 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 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. 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.*