

## Inventiva announces the positive recommendation of the fifth DMC of the NATiV3 Phase 3 clinical trial with lanifibranor in patients with MASH

- ▶ The Data Monitoring Committee recommended to continue the clinical trial without modification of the current protocol, based on the pre-planned review of safety data.
- ▶ The recommendation was based on the unblinded review by the DMC of safety data from more than 1000 patients randomized in the main and exploratory cohorts, including over 800 and 170 patients that have been treated for more than 24 and 72 weeks, respectively.
- ▶ This fifth DMC review confirms the good safety profile of lanifibranor.

**Daix (France), Long Island City (New York, United States), October 30, 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 announced the positive recommendation from the fifth scheduled meeting of the Data Monitoring Committee (“DMC”) to continue the NATiV3 Phase 3 clinical trial evaluating lanifibranor in patients with MASH without modification to the current trial protocol.

The independent group of experts conducted its review based on the unblinded safety data from more than 1000 patients randomized in the main cohort and in the exploratory cohort.

Among the more than 1000 patients whose data was reviewed, over 800 patients have been treated for more than 24 weeks, the treatment duration evaluated in the Phase 2b, NATiVE, study, and 177 patients have been treated for more than 72 weeks. The safety data was unblinded to the DMC but remains blinded with respect to the Company. The DMC review supports the continuation of the NATiV3 clinical trial without modification to the current trial protocol. This positive recommendation confirms the good safety and tolerability profile of lanifibranor.

### About lanifibranor

Lanifibranor, Inventiva’s lead product candidate, is an orally-available small molecule that acts to induce anti-fibrotic, 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. 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.

## 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 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 MASH, 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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## 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 pre-clinical programs and clinical trials, including design, protocol, duration, timing, recruitment costs, screening and enrollment for those trials, including the ongoing NATiV3 Phase 3 clinical trial with lanifibranor in MASH, including the possibility for patients to participate in those trials, the clinical development of and regulatory plans and pathway for lanifibranor, clinical trial data releases and publications, the information, insights and impacts that may be gathered from clinical trials, the safety and tolerability profile and the potential therapeutic benefits of Inventiva's product candidates, including lanifibranor, potential regulatory submissions, approvals, including potential accelerated approval in the United States and conditional approval Europe, and commercialization, Inventiva's pipeline and preclinical and clinical development plans, the expected benefit of having received*

*Breakthrough Therapy Designation, including its impact on the development and review timeline of Inventiva's product candidates, the potential development of and regulatory pathway for odiparcil, and future activities, expectations, plans, growth and prospects of Inventiva and its partners. 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 interim data or data from any interim analysis of ongoing clinical trials may not be predictive of future trial results, the recommendation of the DMC may not be indicative of a potential marketing approval, Inventiva cannot provide assurance on the impacts of the Suspected Unexpected Serious Adverse Reaction (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 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 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.*