PRESS RELEASE

Inventiva announces completion of enrollment in the Phase 3 NATiV3 clinical trial of lanifibranor in patients with MASH and advanced fibrosis

- Target enrollment exceeded with 1009 patients randomized in the main cohort and 410 patients in the exploratory cohort
- Topline results from NATiV3 projected in the second half of 2026 and, if positive, expected to be the basis for submission for regulatory approval

Daix (France), New York City (New York, United States), April 1, 2025 – 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 metabolic dysfunction-associated steatohepatitis ("MASH") and other diseases with significant unmet medical needs, today announced the completion of patient enrollment in its NATiV3 Phase 3 clinical trial with the randomization of the last patient in the main cohort. Inventiva has enrolled 1009 patients in the main cohort and 410 patients in the exploratory cohort exceeding the original target of 969 and 350, respectively.

Frederic Cren, CEO and cofounder of Inventiva, stated: "*The completion of enrollment of NATiV3 marks a significant milestone in the development of lanifibranor. With topline results expected in the second half of 2026, lanifibranor could potentially be the next oral therapy approved for the treatment of patients with MASH. On behalf of the entire Inventiva team, I would like to express our deepest gratitude to the patients, investigators and staff at clinical trial sites participating in the NATiV3 trial worldwide, our partners and collaborators whose commitment has made it possible to reach this major milestone. I would also like to thank the Inventiva team who have dedicated themselves to the achievement of this critical milestone.*"

Prof. Arun Sanyal, M.D., Director of the Stravitz-Sanyal Institute for Liver Disease and Metabolic Health, Virginia Commonwealth University and co-principal investigator of NATiV3, stated: "*The compelling data from the NATIVE Phase 2b trial of lanifibranor after just six months of treatment, instill strong confidence in the potential of lanifibranor to become a cornerstone therapy for patients with MASH, if approved. The unmet medical need for patients with MASH is significant, and lanifibranor's unique mechanism of action could offer a tailored and promising potential solution, particularly for patients with advanced fibrosis and type 2 diabetes. I am eager to see the topline results and look forward to collaborating closely with Inventiva to ensure a successful NDA filing.*"

Topline results of NATiV3 are expected in the second half of 2026.

Completion of enrollment in NATiV3 supports satisfaction of certain conditions related to the second tranche of approximately €116 million of the structured financing announced in October 2024 of up to €348 million, including: (i) the last patient in the NATiV3 main cohort randomized before April 30, 2025 and (ii) at the time of completion of enrollment in NATiV3, a drop-out rate of less than 30% before week 72. The second tranche of the structured financing is subject to additional conditions as set forth in the subscription agreements and there can be no guarantee that all conditions will be satisfied or that the second tranche or any further tranches of the structured financing will close on the expected timing or at all[1].

About NATiV3

[1] See Inventiva press release October 14, 2024 and T1 Subscription Agreement, as filed with the U.S. Securities and Exchange Commission as Exhibit 99.1 to Form 6-K dated October 15, 2024, for further description and a copy of the structured financing agreement.

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 1009 adult patients with biopsy-proven non-cirrhotic MASH and F2/F3 stage of liver fibrosis. The effect of lanifibranor will be assessed on several histological endpoints, including MASH resolution and improvement of fibrosis of at least one stage after 72 weeks treatment. An exploratory cohort has enrolled 410 patients with MASH 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 regulatory approval of lanifibranor for the treatment of MASH. For more information about NATiV3, visit clinicaltrials.gov.

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 PPARα and PPARδ, and a partial activation of PPARγ. 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 preclinical 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 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).
http://www.inventivapharma.com

Contacts

Inventiva
Pascaline Clerc
EVP, Strategy and Corporate Affairs
media@inventivapharma.com
+1 202 499 8937

Brunswick Group
Tristan Roquet Montegon /
Aude Lepreux /
Julia Cailleteau
Media relations
inventiva@brunswickgroup.com
+33 1 53 96 83 83

ICR Healthcare
Patricia L. Bank
Investor relations
patti.bank@icrhealthcare.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, forecasts and estimates with respect to 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, forecasts and estimates with respect to Inventiva's NATiV3 Phase 3 clinical trial with lanifibranor in patients with MASH, including design, protocol, duration, timing and costs of Inventiva's studies, and the results 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, the clinical development of and regulatory plans and pathway for lanifibranor, and future activities, expectations, plans, growth and prospects of Inventiva and its partners, and the absence of material adverse events. 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 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 DSMB 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 the results or timing of the NATiV3 trial or regulatory matters with respect thereto, 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, 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 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 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, 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 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, 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. 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.