

## Inventiva and Hepalys Pharma, Inc. announce the initiation of the clinical development program of lanifibranor in Japan with the dosing of the first participant in Phase 1 trial

- ▶ Initiation of the clinical development program of lanifibranor in Japan with the dosing of the first participant in Phase 1 study
- ▶ Positive results could support the initiation of a pivotal Phase 3 trial in patients in Japan with MASH
- ▶ The study represents the first significant step of Inventiva's and Hepalys's partnership toward the development of lanifibranor in Japan and South Korea

**Daix (France), New York City (New York, United States), Tokyo (Japan), February 20, 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, and Hepalys Pharma, Inc. (“Hepalys”), a company incorporated in Japan and founded by Catalys Pacific, announced today the initiation of the clinical development program of lanifibranor in Japan with the first Japanese participant dosed in a Phase 1 clinical trial evaluating the safety, tolerability, pharmacokinetics (“PK”) and pharmacodynamics (“PD”) of lanifibranor.

As part of the single-center study, 32 subjects will be separated randomly into four cohorts and will receive lanifibranor once daily for 14 days.

The trial is conducted pursuant to the terms of the exclusive licensing agreement entered into in 2023 between Inventiva and Hepalys to develop and commercialize lanifibranor in Japan and South Korea<sup>1</sup>. Under the terms of the agreement, Hepalys is responsible for conducting and financing all trials in Japan and South Korea needed to file for a new drug application in these territories. Positive results from this trial could support the initiation of a pivotal Phase 3 trial in patients in Japan with MASH, once the results of NATiv3, the pivotal Phase 3 trial currently conducted by Inventiva, are available.

The trial represents a key first step in Inventiva's and Hepalys's partnership, as the companies aim to enter the Japanese market with lanifibranor, if approved, where up to 2.7%<sup>2</sup> of the Japanese population suffer from MASH.

**Frederic Cren, CEO and cofounder of Inventiva, stated:** *“The inclusion of the first participant in the Phase 1 study in Japan testifies to the strength of our partnership with Hepalys as we progress with the development of lanifibranor with our goal to make it accessible to a significant number of MASH patients. The partnership with Hepalys enables us to start development in a key market such as Japan, where our partner's local expertise is key to the program's success.”*

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<sup>1</sup> [Press release September 20, 2023](#)

<sup>2</sup> Eguchi Y, Wong G, Lee EI, Akhtar O, Lopes R, Sumida Y. Epidemiology of non-alcoholic fatty liver disease and non-alcoholic steatohepatitis in Japan: A focused literature review. JGH Open. 2020 May 5;4(5):808-817.

**BT Slingsby, MD, PhD, MPH, Representative Director of Hepalys Pharma, Inc., stated:** *“It has been an exciting build-up of the clinical program for lanifibranor, and we are thrilled about the first participant dosed in this Phase 1 clinical trial, which is a key first step in the progression of our clinical development planned for lanifibranor. If successful, it will propel our work in potentially launching this drug candidate in Japan, as a potentially life-saving treatment for patients with MASH. We look forward to the ongoing dosing of patients and to results from this trial.”*

#### About Hepalys Pharma, Inc.

Hepalys Pharma, Inc. is a private venture-backed biopharmaceutical company focused on the development of novel therapeutics for liver disease, led by a world-class team and a transpacific clinical advisory board, committed to develop and commercialize lanifibranor and potentially other compounds for patients in Asian countries. Hepalys is headquartered in Tokyo, Japan.

#### About Catalys Pacific

Catalys Pacific is a transpacific life sciences investment firm that provides solutions for patients worldwide through the creation of investments in biopharma companies. Catalys Pacific is led by a team of entrepreneurs and investors who work closely with partners in academia, venture capital, and the pharmaceutical industry. The firm maintains offices in Japan and the West Coast of the US. For more information, visit [catalyspacific.com](http://catalyspacific.com).

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

## Contacts

### Inventiva

Pascaline Clerc, PhD  
EVP, Strategy and Corporate Affairs  
[media@inventivapharma.com](mailto:media@inventivapharma.com)  
+1 202 499 8937

### Brunswick Group

Tristan Roquet Montegon /  
Aude Lepreux /  
Julia Cailleteau  
Media relations  
[inventiva@brunswickgroup.com](mailto:inventiva@brunswickgroup.com)  
+33 1 53 96 83 83

### ICR Healthcare

Patricia L. Bank  
Investor relations  
[patti.bank@icrhealthcare.com](mailto:patti.bank@icrhealthcare.com)  
+1 415 513 1284

## Important Notice

*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, forecasts and estimates with respect to ongoing and planned clinical trials conducted by Inventiva and its partners, including design, duration, timing, recruitment costs, screening and enrollment for those trials, including Inventiva’s NATiV3 Phase 3 clinical trial with lanifibranor in MASH and Hepalys’s Phase 1 trial of lanifibranor in Japan, clinical trial data releases and publications, the information, insights and impacts that may be gathered from clinical trials, the potential therapeutic benefits of lanifibranor, expectations with respect to clinical development and commercialization by Hepalys, including with respect to clinical trials, regulatory approvals, the expected benefit of having received Breakthrough Therapy Designation and Fast Track Designation, including its impact on the development and review timeline of Inventiva’s product candidates and approvals, the rights and obligations under agreements with Hepalys Pharma Inc., and Inventiva’s future activities, expectations, plans, growth, potential revenues and prospects. 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”, 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 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 ability to satisfy in part or full the closing conditions for subsequent tranches of the structured financing announced on October 14, 2024 (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, 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 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. 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.*

*Please note that this press release does not pertain to conditions precedent relating to the €348 million Structured Financing announced on October 14, 2024. Important information relating to the second tranche of the financing will be the subject of a press release from the Company at the applicable time.*