

# Inventiva provides an update on the development of cedirogant by AbbVie

**Daix (France), Long Island City (New York, United States), October 31, 2022** – Inventiva (Euronext Paris and Nasdaq: IVA), a clinical-stage biopharmaceutical company focused on the development of oral small molecule therapies for the treatment of non-alcoholic steatohepatitis (NASH), mucopolysaccharidoses (MPS) and other diseases with significant unmet medical needs, today announced that AbbVie communicated during their third-quarter financial results<sup>1</sup> on Friday October 28<sup>th</sup>, that they decided to stop the development of cedirogant (ABBV-157), an oral RORγ inverse agonist jointly discovered by Inventiva and AbbVie for the treatment of autoimmune diseases, following the analysis of a recently concluded nonclinical toxicology study.

The Company's cash runway, including the expected \$12 million upfront payment from Sino Biopharm and the €25 million from the EIB credit facility<sup>2</sup>, is not impacted by the discontinuation of the cedirogant clinical program and should allow to fund as previously announced operations through Q4 2023<sup>3</sup>. Inventiva's R&D capabilities and objectives remain unaltered.

**Frédéric Cren, Chairman, Chief Executive Officer and cofounder of Inventiva, stated:** *"Although we are disappointed to see the end of cedirogant's clinical program following the analysis of a nonclinical toxicology study, we wish to thank our partner AbbVie for 10 years of collaboration. We are now fully focused on the development of our lead asset lanifibranor, a promising treatment which is currently in Phase III clinical development for the treatment of NASH, a disease for which there are currently no treatments approved by regulatory agencies. We continue to make progress in our NATiV3 pivotal Phase III trial and we recently reached a major milestone in this respect by entering into a partnership with Sino Biopharm, a leading Chinese pharmaceutical group, to develop and potentially commercialize lanifibranor in Greater China."* 

In 2012, Inventiva and AbbVie signed a multi-year drug discovery collaboration agreement to identify potent ROR $\gamma$  inverse agonists for the treatment of several autoimmune diseases. Inventiva's and AbbVie's joint efforts led to the discovery of cedirogant, which was being evaluated in a Phase II clinical trial at the time of AbbVie's decision to discontinue further clinical development.

### **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 NASH, MPS 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 patients with NASH, a common and progressive chronic liver disease for which there are currently no approved therapies. In 2020, Inventiva announced positive topline data from its Phase IIb clinical trial

<sup>&</sup>lt;sup>1</sup> <u>Q3 2022 AbbVie Inc. Earnings Conference Call (media-server.com)</u>

<sup>&</sup>lt;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>&</sup>lt;sup>3</sup> Inventiva-PR-H1-2022-EN-22092022-FINAL-2.pdf (inventivapharma.com)



evaluating lanifibranor for the treatment of adult patients with NASH and obtained both FDA Breakthrough Therapy and Fast Track designation for lanifibranor in the treatment of NASH. Lanifibranor is currently being evaluated in a pivotal Phase III clinical trial.

Inventiva's pipeline also includes odiparcil, a drug candidate for the treatment of adult mucopolysaccharidoses (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 an oncology development candidate for its Hippo signaling pathway program.

The Company has a scientific team of approximately 80 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 C 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, forecasts and estimates with respect to Inventiva's pre-clinical programs and clinical trials, including recruitment, screening and enrolment for those trials, including the NATiV3 Phase III clinical trial with lanifibranor in 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 lanifibranor, pipeline and preclinical and clinical development plans, future activities, expectations, plans, growth and prospects of Inventiva and the sufficiency of Inventiva's cash resources and cash runway. 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", "plans", "designed", "hopefully", "target", "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. Future 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

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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 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, 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 clinical trials may not support Inventiva's product candidate claims, Inventiva may encounter substantial delays in its clinical trials or Inventiva may fail to demonstrate safety and efficacy to the satisfaction of applicable regulatory authorities, enrolment 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 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, and preclinical studies and clinical development programs and timelines, its financial condition and results of operations could be materially and adversely affected by the current COVID-19 pandemic and geopolitical events, such as the conflict between Russia and Ukraine, related sanctions and related impacts and potential impacts on the initiation, enrolment and completion of Inventiva's clinical trials on anticipated timelines, and macroeconomic conditions, including global inflation and uncertain financial markets. 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, 2021 filed with the Autorité des Marchés Financiers on March 11, 2022, the Annual Report on Form 20-F for the year ended December 31, 2021 filed with the Securities and Exchange Commission on March 11, 2022 and the financial report for the first half of 2022 filed Securities and Exchange Commission on September 22, 2022 for additional information in relation to such factors, risks and uncertainties.

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.