

# Inventiva announces that its partner Sino Biopharm received IND approval from the NMPA to initiate clinical trial with lanifibranor in China

- ► Chia Tai Tianqing Pharmaceutical Group Co., Ltd., a Sino Biopharm's subsidiary, receives IND approval from the NMPA to initiate the clinical development in mainland China of lanifibranor in NASH
- ► Sino Biopharm will participate in the ongoing NATiV3 Phase III trial which, if positive, is expected to support a potential NDA filing in China
- ► In parallel, Sino Biopharm will conduct a Phase I clinical pharmacology study
- ► Following this regulatory decision, Inventiva is eligible to the first of the 2 short term milestones amounting to a total of \$5 million, under the license and collaboration agreement with CTTQ

Daix (France), Long Island City (New York, United States), Beijing/Hong Kong (China), May 25, 2023 – 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") and other diseases with significant unmet medical needs, and Sino Biopharm, through its subsidiary Chia Tai Tianqing Pharmaceutical Group Co., Ltd. ("CTTQ"), today announce that CTTQ received Investigational New Drug ("IND") approval from the Chinese National Medical Products Administration ("NMPA") on May 22<sup>nd</sup> 2023, and can now initiate the clinical development of Inventiva's lead compound lanifibranor in mainland China.

Frederic Cren, CEO and cofounder of Inventiva, stated: "We are extremely pleased by this positive feedback from the NMPA, which allows our lead compound to advance into a Phase III clinical trial in NASH in mainland China. This is an important milestone for us and our partner Sino Biopharm, and brings new opportunities for patients affected by NASH in China to participate in the global NATiV3 Phase III clinical trial. We are looking to successfully develop lanifibranor with Sino Biopharm and potentially commercialize in China the first oral treatment for patients with NASH."

Philip Duong, Head of Overseas BD & Alliance, Sino Biopharm: "We are delighted to have received the IND approval from the Chinese NMPA. This positive step brings us one step closer to potentially bringing a NASH product candidate to patients with NASH in China, a growing and devastating disease with no product currently approved. With its broad mechanism of action acting on the spectrum of NASH disease, we believe that lanifibranor could potentially be one of the best-in-class treatments for the estimated 32 million patients with NASH in China. Our entire team is now looking forward to next steps and participating in NATiV3."

Under the proposed clinical program, CTTQ will enrol patients from China in the global ongoing NATiV3 Phase III clinical trial, which, if positive, is expected to support a potential New Drug Application ("NDA") filing in China, the United States and Europe. In addition, CTTQ will also conduct in parallel a Phase I clinical pharmacology study to evaluate the pharmacokinetics of the 800mg/day and 1200mg/day doses of lanifibranor in healthy Chinese subjects. CTTQ will be responsible for all costs linked to lanifibranor development in China. Following the IND approval, Inventiva is eligible to the first of the 2 short term milestones amounting to a total of \$5 million, under the license and collaboration agreement with CTTQ.



### **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, mucopolysaccharidoses ("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 adult patients with NASH, a common and progressive chronic liver disease for which there are currently no approved therapies.

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 an oncology development candidate for its Hippo signalling 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

# **About Sino Biopharm**

Sino Biopharm is a leading, innovative R&D-driven pharmaceutical conglomerate in China. Its business encompasses a fully-integrated chain which covers an array of R&D platforms, a line-up of intelligent production and a strong sales system. Sino Biopharm's products have gained a competitive foothold in various therapeutic categories with promising potential, comprising a variety of biopharmaceutical and chemical medicines for oncology, surgery/orthopedics, liver disease, and respiratory system. The collaboration with Inventiva is managed by invoX Pharma Limited ("invoX"), a wholly owned subsidiary of Sino Biopharm, headquartered in the United Kingdom. invoX is Sino Biopharm's international expansion platform, focusing on R&D and business development activities outside of China.

For further information about Sino Biopharm, please visit: http://www.sinobiopharm.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 $\alpha$ , and a partial activation of PPAR $\alpha$ . While there are other PPAR agonists that target only one or two PPAR isoforms for activation, lanifibranor is the most advanced pan-PPAR agonist in clinical development for the treatment of 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 NASH.

#### **Contacts**

| Inventiva   | Sino Biopharm  |
|---|--|
| Pascaline Clerc  VP of Global External Affairs  media@inventivapharma.com  +1 240 620 9175                                      | Philip Duong,  Head of Overseas BD & Alliance  Philip.duong@sino-biopharm.com  +86 136 2238 0450 |
|   | Kyler Lei Head of Capital Markets kylerlei@sino-biopharm.com +86 138 038 11366                   |
| Brunswick Group   | Westwicke, an ICR Company  |
| Tristan Roquet Montegon, Aude Lepreux, Matthieu Benoist<br>Media relations<br>inventiva@brunswickgroup.com<br>+33 1 53 96 83 83 | Patricia L. Bank Investor relations patti.bank@westwicke.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 Inventiva's pre-clinical programs and clinical trials, including design, duration, timing, recruitment costs, screening and enrolment for those trials, including the ongoing NATiV3 Phase III clinical trial with lanifibranor in NASH, the clinical development and regulatory plans for lanifibranor of Sino Biopharm and its affiliates, including the planned Phase III clinical trial in patients with NASH, the Phase I clinical pharmacology study of lanifibranor in healthy Chinese subjects, the potential for lanifibranor to be one of the bestin-class treatments for the patients with NASH in China, the estimated number of patients with NASH in China, 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 Inventiva's product candidates, including lanifibranor, potential regulatory submissions and approvals, including a potential NDA filing in China, the United States and Europe, Inventiva's pipeline and preclinical and clinical development plans, Inventiva's collaboration with CTTQ, future activities, expectations, plans, growth and prospects of Inventiva, and milestone payments, including milestone payments from CTTQ, and the potential of Sino Biopharm's products and future activities, expectations, plans, growth and prospects of Sino Biopharm. 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", "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 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 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 the changes to the clinical development plan for lanifibranor for the treatment of NASH may not be realized and may not support the approval of a New Drug Application, Inventiva and its partners may encounter substantial delays in its clinical trials or Inventiva may 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, 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 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 and its partners' clinical trials on anticipated timelines, 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, 2022 filed with the Autorité des Marchés Financiers on March 30, 2023, and the Annual Report on Form 20-F for the year ended December 31, 2022 filed with the Securities and Exchange Commission on March 30, 2023 for other risks and uncertainties affecting Inventiva, including those described from time to time under the caption "Risk Factors". 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.