

# Inventiva and Sino Biopharm announce licensing and collaboration agreement to develop and commercialize lanifibranor in Greater China

- Sino Biopharm a leading Chinese pharmaceutical group, through CTTQ will oversee the development and commercialization of lanifibranor in Greater China
- Lanifibranor is an orally-available small molecule with breakthrough therapy designation from the U.S. Food and Drug Administration ("FDA") following a positive Phase 2b trial in patients with non-alcoholic steatohepatitis ("NASH"). Lanifibranor is currently being evaluated in a Phase 3 trial in NASH
- Inventiva will receive a \$12 million upfront payment, with the right to receive \$5 million in potential milestone payments, up to \$290 million of clinical, regulatory and commercial milestone payments, in addition to tiered royalties on net sales of lanifibranor in Greater China

Daix (France), Long Island City (New York, United States), Beijing/Hong Kong (China), September 21 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 and other diseases with significant unmet medical needs, and Chia Tai-Tianqing Pharmaceutical Group Co., Ltd ("CTTQ"), a subsidiary of Sino Biopharm, have entered into a licensing and collaboration agreement (the "Agreement") to develop and commercialize lanifibranor, if approved, Inventiva's proprietary compound, for the treatment of non-alcoholic steatohepatitis and potentially other metabolic diseases in mainland China, Hong Kong, Macau and Taiwan ("Greater China").

**Frederic Cren, CEO and cofounder of Inventiva, stated**: "This agreement with Sino Biopharm represents an important milestone not only to support and accelerate the development of lanifibranor, but also to potentially develop and commercialize lanifibranor in Greater China, a region which has a similar prevalence of NASH to the U.S. and a large number of untreated patients at risk of progressing to cirrhosis. Moreover, this agreement could make a significant contribution to the reinforcement of our cash position. We are particularly proud of partnering with Sino Biopharm, a company with a strong presence in the hepatology field and a clear motivation and strategy to make lanifibranor a potential treatment option for patients with NASH in Greater China."

**Theresa Tse, Chairwoman, Sino Biopharm**: "This agreement is further evidence of Sino Biopharm's commitment to seeking innovation, in one of our core therapeutics areas, liver disease. We have been at the forefront in helping China eliminate hepatitis B for over a decade, and today, NASH without any approved treatments, is the fastest growing cause of liver transplants and liver cancer, so we are delighted to enter into this agreement with Inventiva, which is a great opportunity to potentially bring a promising and convenient treatment of NASH to China."

**Sean Chen, Chief Strategy Officer, Sino Biopharm**: "Sino Biopharm ranks top in China on liver disease drug sales and we believe this collaboration on lanifibranor, a potential best-in-class pan-PPAR agonist for the treatment of NASH, will further enrich our innovative pipeline on liver disease and strengthen our leadership in this



therapeutic area. Our team is looking forward to partnering with Inventiva to accelerate the development of Lanifibranor in China and to satisfy an unmet clinical need in the quickest possible timeframe."

In exchange for receiving an exclusive license to develop, import, manufacture, commercialize and market lanifibranor in Greater China, CTTQ will pay Inventiva an upfront payment of \$12 million and an additional \$5 million if certain clinical milestones are met. Under the terms of the Agreement, Inventiva has the potential to receive up to \$290 million of clinical, regulatory and commercial milestone payments. In addition, subject to regulatory approval, Inventiva will receive tiered royalties from high single-digit to mid-teen double digits of net sales made by Sino Biopharm in Greater China during the first three years of commercialization and from low to mid-teen double digits starting from year four. Depending on multiple factors, including Chinese regulatory authority feedback, it is anticipated that CTTQ will either join the ongoing NATiV3 Phase III clinical trial of lanifibranor in NASH or run an independent study. CTTQ will bear all costs associated with the trials conducted in Greater China.

## 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 needs. The Company benefits from a strong expertise and experience in the domain of compounds targeting nuclear receptors, transcription factors and epigenetic modulation. 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.

The Company has established a strategic collaboration with AbbVie in the area of autoimmune diseases that resulted in the discovery of the drug candidate cedirogant (ABBV-157), an oral RORy inverse agonist which is being evaluated in a Phase IIb clinical trial, led by AbbVie, in adult patients with moderate to severe chronic plaque psoriasis. 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 in the process of selecting an oncology development candidate for its Hippo signalling 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.

#### **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, headquarter 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 $\delta$ , 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 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.

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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, potentially bringing a promising and convenient treatment of NASH to China, the ability to accelerate the development of lanifibranor in Greater China and to satisfy an unmet clinical need and make lanifibranor a potential treatment option for patients with NASH in Greater China, forecasts and estimates with respect to Inventiva's pre-clinical programs and clinical trials, including the design, timing, progress and number of patients to be recruited for those trials, including the NATiV3 Phase III clinical trial with lanifibranor in NASH and the expected Phase IIb clinical trial of cedirogant led by AbbVie, measures to decrease the screen failure rate or increase the enrollment rate or have other intended impacts on the NATiV3 Phase III clinical trial and the timing of the NATiV3 Phase III clinical trial may be further delayed, potential development of odiparcil and lanifibranor, clinical trial data releases and publications, the information, insights and impacts that may be gathered from clinical trials, including the NATiV3 Phase III clinical trial with lanifibranor in NASH and the planned expansion of the NATiV3 Phase III clinical trial or independent study in Greater China through the Agreement, the potential

# **PRESS RELEASE**



marketing and therapeutic potential of lanifibranor and other product candidates, pipeline and preclinical and clinical development plans, milestone payments, including milestone payments from Sino Biopharm, royalties and product sales, potential proceeds under the Company's financing arrangements, 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" and "continue" and similar expressions. Such statements are not historical facts but rather are statements of future expectations and other forwardlooking 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 quarantees 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. 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, Inventiva's ability to obtain regulatory approval and subsequent commercialization of current and any future product candidates, including the commercialization of product candidates in China, 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's ability to meet the conditions to receive clinical, regulatory and commercial milestone or royalty payments under the agreements with its commercial partners, 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, the ability of Inventiva and Sino Biopharm 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 and Sino Biopharm'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's ability, and that of its commercial partners, to execute their commercialization strategy for approved products, 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 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 and 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 First Half Report for the six months ended June 30, 2022 to be filed with the SEC, 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.