Inventiva and Hepalys Pharma, Inc. announce exclusive licensing agreement to develop and commercialize lanifibranor in Japan and South Korea

- Hepalys Pharma, Inc. is a new company created by Catalys Pacific and in which Inventiva has a 30% ownership position.
- Under the exclusive licensing agreement, Inventiva will receive a $10 million upfront payment, and is eligible to receive up to $ 231 million in clinical, regulatory and commercial milestone payments in addition to tiered royalties from mid double digits to low twenties based on net sales of lanifibranor in Japan and South Korea.
- Pending regulatory approvals, Hepalys Pharma, Inc. is expected to initiate Phase I PKPD studies in Japanese patients and healthy volunteers and will be responsible for funding all studies of lanifibranor necessary to file for a new drug application in Japan and South Korea.
- In addition to the 30% of shares of Hepalys Pharma, Inc., Inventiva already owns, Inventiva has the option to acquire all outstanding shares of Hepalys Pharma, Inc., at a pre-agreed multiple of post-money valuation.
- In the event Hepalys receives an offer to sell the license or rights related to lanifibranor, Inventiva has a right of first refusal.

Daix (France), Long Island City (New York, United States), Tokyo (Japan), September 20 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 Hepalys Pharma, Inc., a company incorporated in Japan and incubated by Catalys Pacific, have entered into an exclusive licensing agreement (the "Agreement") to develop and commercialize Inventiva's proprietary drug candidate lanifibranor for the treatment of non-alcoholic steatohepatitis (NASH) in Japan and South Korea.

Hepalys Pharma is a new company founded by Catalys Pacific, an investment firm specialized in creating and financing venture capital-backed biopharmaceutical companies to develop pharmaceutical products in Asia. Hepalys Pharma is backed by renowned investors including Catalys Pacific, Mitsubishi UFJ Capital, DBJ Capital, and MEDIPAL Innovation Fund.

In parallel of the incorporation of Hepalys Pharma, Inventiva has exercised its right to own 30% of the company.

Under the terms of this licensing agreement, Inventiva will receive a $10 million upfront payment from Hepalys Pharma and will be eligible to receive up to $231 million in milestone payments if certain clinical, regulatory and

commercial conditions are met. Subject to regulatory approval, Inventiva has the right to receive tiered royalties from mid double digits to low twenties based on net sales of lanifibranor in Japan and South Korea.

In addition, under the terms of this agreement, Inventiva has the option to acquire the outstanding shares of Hepalys Pharma at a pre-agreed multiple of post-money valuation under certain conditions, and has a right of first refusal if Hepalys Pharma, Inc. receives an offer to sell the license and rights related to lanifibranor.

This agreement is expected to accelerate the time to market of lanifibranor in Japan and South Korea if regulatory approvals are obtained. Both countries are major markets, with up to 2.7%[1] of and up to 5.2%[2] of Japanese and South Koreans, respectively, suffering from NASH, including about 15% of South Korean patients with significant fibrosis. Hepalys Pharma, Inc. is expected to start the clinical development of lanifibranor by conducting two phase I studies in Japanese patients and healthy volunteers. It is anticipated that these studies would support, if positive, the initiation of a dedicated pivotal trial in Japanese and Korean patients with NASH, which is planned to start once the results of NATiV3, the pivotal phase III trial currently conducted by Inventiva, are available. Hepalys Pharma, Inc. will be responsible for conducting and financing all development trials in Japan and South Korea needed to file for a new drug application in these territories.

Frederic Cren, CEO and cofounder of Inventiva, stated: *"We are thrilled to further expand our global reach to Japan and South Korea through this exclusive licensing agreement with Hepalys Pharma, Inc. We strongly believe that Hepalys Pharma, Inc. with its experienced team is the right partner to start and fund the clinical development of lanifibranor in Japan and South Korea. This agreement is a great opportunity for Inventiva to speed up the potential commercialization of its lead asset in these two major markets and diversify our milestones and royalties' source of revenues if regulatory approvals are achieved. With the ongoing partnership in Greater China and this new agreement in Japan and Korea, Inventiva is eligible to receive up to an additional $519M of clinical, regulatory and commercial milestones."*

BT Slingsby, MD, PhD, MPH, Representative Director of Hepalys Pharma, Inc., stated: *"We are delighted to enter into a licensing agreement with Inventiva. We purposely founded Hepalys Pharma, Inc. to conduct the clinical development and potential commercialization of lanifibranor, a drug candidate for the potential treatment of NASH in Japan and Korea. We are confident that, if successful in our clinical programs and if required regulatory approvals are obtained, lanifibranor could potentially become an effective treatment for patients with NASH in Japan and South Korea based on the efficacy demonstrated so far on fibrosis and NASH resolution, and on the cardiometabolic components of the disease. We are looking forward to starting the clinical development program of lanifibranor in Japan and South Korea."*

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 life sciences venture capital firm whose mission is to provide healthcare solutions for patients worldwide through the creation of, and investment in biotech companies. Catalys Pacific is led by a global team versed in working closely with its partners in academia, biotech, venture capital and the pharmaceutical industry worldwide with an emphasis in Japan. The firm maintains offices in Tokyo, Japan and in San Francisco, California.

[1]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.
[2]Park J, Lee EY, Li J, Jun MJ, Yoon E, Ahn SB, Liu C, Yang H, Rui F, Zou B, Henry L, Lee DH, Jun DW, Cheung RC, Nguyen MH. NASH/Liver Fibrosis Prevalence and Incidence of Nonliver Comorbidities among People with NAFLD and Incidence of NAFLD by Metabolic Comorbidities: Lessons from South Korea. Dig Dis. 2021;39(6):634-645.

About lanifibranor

Lanifibranor, Inventiva's lead product candidate, is an orally-available small molecule that acts to induce anti-fibrotic, 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 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.

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 (also known as metabolic dysfunction-associated steatohepatitis (MASH)), 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 signaling 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

Contacts

Inventiva
Pascaline Clerc
VP of Global External Affairs
media@inventivapharma.com
+1 240 620 9175

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

Westwicke, an ICR Company
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, 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, expectations with respect to clinical development and commercialization by Hepalys Pharma, Inc., including with respect to potential clinical trials and regulatory approvals, expectations with respect to the benefits of the agreement with Hepalys Pharma, Inc., including potential acceleration lanifibranor commercialization in the event required regulatory approvals are obtained, potential regulatory submissions and approvals, achievement of milestones, potential milestone payments and potential royalties under the agreement with Hepalys Pharma, Inc., the rights and obligations under agreements with Hepalys Pharma Inc., including Inventiva's right to purchase shares in the company and right of first refusal, and Inventiva's pipeline and preclinical and clinical development plans, 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. 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, 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 clinical trials may not support Inventiva's 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 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, 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 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, 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, 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. Consequently, Inventiva accepts no liability for any consequences arising from the use of any of the above statements.