PRESS RELEASE

Inventiva announces that its IND application for the Phase II combination trial with lanifibranor and empagliflozin in patients with NASH and T2D has been accepted by the FDA

- FDA assessment concludes that the Phase II combination trial, LEGEND, may proceed
- The initiation of the trial is planned for H1 2022 and the publication of topline results is expected for H2 2023

Daix (France), Long Island City (New York, United States), March 8, 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) and other diseases with significant unmet medical needs, today announced that the U.S. Food and Drug Administration (FDA) has completed its safety review of the IND application and has concluded that the proof-of-concept Phase II combination trial with its lead drug candidate lanifibranor and the SGLT2 inhibitor empagliflozin[1] in patients with Type 2 Diabetes (T2D) and non-cirrhotic NASH may proceed.

Pierre Broqua, Chief Scientist Officer and cofounder of Inventiva, stated: *"The FDA's decision to clear our Investigational New Drug submitted for our proof-of–concept study, LEGEND, is an important milestone for the development of lanifibranor. Our Phase IIb[2] has successfully demonstrated that lanifibranor as a monotherapy could not only resolve NASH and improve fibrosis but also improve the lipids and glycemic profiles. We believe that a combination therapy with lanifibranor and empagliflozin can provide additional benefits and further improve the cardiometabolic risk profile of patients with NASH."*

Dr. Onno Holleboom, Internist and endocrinologist at Amsterdam University Medical Centers and co-Principal Investigator of LEGEND: *"As a pan-PPAR agonist acting on the key components of NASH: metabolism, inflammation and fibrosis, lanifibranor is a good candidate for a first-line pharmacology treatment for NASH. However, NASH is a multifaceted disease and the treatment of NASH will naturally evolve to include combination therapies in order to address the full cardiometabolic spectrum of the disease. Combination therapies allow to individualize treatment and improve clinical management of patients and I am excited to assess whether lanifibranor and empagliflozin could potentially lead to such results for patients with T2D and NASH."*

The planned Phase II trial, LEGEND[3], has been designed as a multi-center randomized, placebo-controlled proof-of-concept trial to assess the safety and efficacy of lanifibranor in combination with the SGLT2 inhibitor empagliflozin for the treatment of patients with non-cirrhotic NASH and T2D. The trial is double-blind for the placebo and lanifibranor arms and open-label for the combination of lanifibranor and empagliflozin arm.

LEGEND is expected to recruit a total of 63 patients non-cirrhotic NASH with T2D. The diagnosis of non-cirrhotic NASH will be based on historic histology evaluation or a combination of non-invasive methods including imaging and serum-based metabolic diagnostic tests.

[1] Empagliflozin is marketed under the brand name Jardiance® by Boehringer Ingelheim and Eli Lilly and Company. Jardiance is approved for treating type 2 diabetes and reducing the risk of cardiovascular disease for adults with type 2 diabetes. Lilly reported Jardiance® global sales of $1.15 billion in 2020, while Boehringer posted worldwide Jardiance® sales of €2.48 billion. (Source: Eli Lilly and Boehringer Ingelheim 2020 annual reports).
[2] N Engl J Med 2021; 385:1547-1558.
[3] https://clinicaltrials.gov/ct2/show/NCT05232071.

The primary efficacy endpoint of the trial is a change in Hemoglobin A1c (HbA1c) at the end of the 24-week treatment compared to baseline. Secondary endpoints include changes in liver enzymes, glycaemic and lipids parameters, inflammatory markers and body fat composition. The trial is designed to provide valuable information on body weight evolution and body fat composition in patients with NASH and T2D when treated with lanifibranor and empagliflozin. Magnetic resonance imaging (MRI) will in addition allow to collect non-invasive data on hepatic fat, inflammation and fibrosis.

The initiation of the trial is planned for the first half of 2022 and the publication of top line results is expected for the second half of 2023.

About Inventiva

Inventiva is a clinical-stage biopharmaceutical company focused on the research and development of oral small molecule therapies for the treatment of NASH 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'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 RORγ 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 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 70 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, clinical trial data releases, pipeline and preclinical and clinical development plans, anticipated milestones, milestone payments, royalties and product sales, future activities, expectations, plans and prospects of Inventiva, the sufficiency of Inventiva's cash resources and expectations with respect to the potential commercial success and potential revenues of Inventiva's product candidates. 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", 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, 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, 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 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 COVID-19 pandemic and geopolitical events, such as the conflict between Russia and Ukraine, which could delay the initiation, enrollment and completion of Inventiva's clinical trials on anticipated timelines or at all. 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, 2020 filed with the Autorité des Marchés Financiers on March 15, 2021, the Annual Report on Form 20-F for the year ended December 31, 2020 filed with the Securities and Exchange Commission on March 15, 2021 as well as the half-year financial report for the six months ended June 30, 2021 for additional information in relation to such factors, risks and uncertainties, in addition to the Universal Registration Document for the year ended December 31, 2021 expected to be filed with the Autorité des Marchés Financiers on March 16, 2021 and the Annual Report on Form 20-F for the year ended December 31, 2021 expected to be filed with the Securities and Exchange Commission on March 16, 2021.

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.