

Inventiva announces FDA decision that Fast Track designation granted to lanifibranor in NASH encompasses the treatment of NASH with compensated cirrhosis

- ▶ The FDA decision follows the Company's Fast Track designation request for lanifibranor in NASH with compensated cirrhosis filed in August 2021

Daix (France), Long Island City (New York, United States), September 21, 2021 – 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 need, today announced that the U.S. Food and Drug Administration (FDA) has decided that the Fast Track designation previously granted to lanifibranor in NASH encompasses the treatment of NASH patients with compensated cirrhosis.

This decision follows a Fast Track designation request for lanifibranor in NASH with compensated cirrhosis filed by Inventiva with the FDA in August 2021. Previously, the FDA had granted both Fast Track and Breakthrough Therapy designations to lanifibranor for the treatment of NASH in September 2019 and October 2020, respectively.

The FDA's dedicated Fast Track program is designed to facilitate the development and expedite the review and potential approval of drug candidates demonstrating the capacity to treat serious conditions and fill significant unmet medical needs.

Pierre Broqua, Ph.D., Chief Scientific Officer and cofounder of Inventiva, commented: *"We are delighted to have a Fast Track designation for lanifibranor in NASH that extends to the treatment of NASH with compensated cirrhosis, a very severe stage of the disease where patients are in urgent need of treatment. The FDA decision does not only recognize this urgency but also the potential of lanifibranor to address this crucial unmet medical need. This news reinforces our confidence in the unique mechanism of action of our lead drug candidate and confirms our determination to accelerate the development of lanifibranor in its pivotal phase."*

NASH with compensated cirrhosis represents a serious stage of the disease and is becoming the leading cause for liver transplantation, which today represents the only available treatment option for patients who have progressed to end-stage NASH. There is thus an urgent need to develop pharmacological therapies to slow down or halt the progression towards NASH with compensated cirrhosis for NASH patients who are at an increased risk of liver-related morbidity and mortality.

Given the broad range of activity of lanifibranor as a pan-PPAR agonist on multiple features of NASH, including beneficial effects on metabolism, inflammation, ballooning, fibrosis and vascular manifestations, Inventiva believes that there is a strong rationale to evaluate the efficacy of lanifibranor in NASH patients with compensated cirrhosis.

About Fast Track designation¹

Fast track is a process designed to facilitate the development and expedite the review and potential approval of drug candidates to treat serious, life-threatening conditions and fill an unmet medical need. The purpose is to get important new drugs to the patient earlier.

Determining whether a condition is serious is a matter of judgment, but generally is based on whether the drug will have an impact on factors such as survival, day-to-day functioning, or the likelihood that the condition, if left untreated, will progress from a less severe condition to a more serious one.

Filling an unmet medical need is defined as providing a therapy where none exists or providing a therapy which may be potentially better than available therapy. Any drug being developed to treat or prevent a condition with no current therapy is obviously directed at an unmet need. If there are available therapies, a Fast Track drug must show some advantage over available therapy, which is assessed against a pre-defined set of criteria.

About Inventiva

Inventiva is a clinical-stage biopharmaceutical company focused on the development of oral small molecule therapies for the treatment of NASH, MPS and other diseases with significant unmet medical need.

Leveraging its expertise and experience in the domain of compounds targeting nuclear receptors, transcription factors and epigenetic modulation, Inventiva is currently advancing two clinical candidates, as well as a deep pipeline of preclinical programs.

Lanifibranor, its lead product candidate, is being developed 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 evaluating lanifibranor for the treatment of 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 is also developing odiparcil, a second clinical stage asset, for the treatment of patients with subtypes of MPS, a group of rare genetic disorders. Inventiva announced positive topline data from its Phase IIa clinical trial evaluating odiparcil for the treatment of adult MPS VI patients in 2019 and received both FDA Fast Track and Rare Paediatric Disease designation for odiparcil in MPS VI.

In parallel, Inventiva is in the process of selecting an oncology development candidate for its Hippo signalling pathway program. Furthermore, the Company has established a strategic collaboration with AbbVie in the area of autoimmune diseases. AbbVie has started the clinical development of ABBV-157, a drug candidate for the treatment of moderate to severe psoriasis resulting from its collaboration with Inventiva. This collaboration enables Inventiva to receive milestone payments upon the achievement of pre-clinical, clinical, regulatory and commercial milestones, in addition to royalties on any approved products resulting from the collaboration.

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, as well as in clinical development. It also 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: FRO013233012) and on the Nasdaq Global Market in the United States (ticker: IVA). www.inventivapharma.com.

¹ <https://www.fda.gov/patients/fast-track-breakthrough-therapy-accelerated-approval-priority-review/fast-track> (12/09/2019).

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Important Notice

This press release contains forward-looking statements, forecasts and estimates with respect to Inventiva's clinical trials, clinical development plans and anticipated future activities of Inventiva. 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" 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 the potential benefits Inventiva may realize from Fast Track designation granted to lanifibranor, its ability to accelerate the development of lanifibranor, or that lanifibranor will receive the necessary regulatory approvals. 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 current COVID-19 pandemic. 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, Amendment No. 1 to the Annual Report on Form 20-F for the year ended December 31, 2020 filed with the Securities and Exchange Commission on March 24, 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.

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.