

## Inventiva announces positive results of clinical thorough QT study conducted with lanifibranor

- ▶ Trial conducted in 217 patients to evaluate the potential effect of lanifibranor on the QT/QTc interval in healthy subjects and to support lanifibranor New Drug Application (NDA) package in NASH
- ▶ Lanifibranor administered at the anticipated maximal therapeutic dose of 1200mg/day and at the supra-therapeutic dose of 2400mg/day had no impact on QT/QTc interval

**Daix (France), Long Island City (New York, United States), December 6, 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 needs, today announced the results of a clinical thorough QT/QTc study<sup>1</sup> demonstrating the safety of lanifibranor on cardiac electrical activity.

The assessment of lanifibranor on cardiac repolarization was conducted in accordance with Food and Drug Administration guidance<sup>2</sup> (FDA) in a phase I double-blind clinical trial to be included in the NDA package of lanifibranor for the treatment of NASH. The clinical trial enrolled 217 healthy subjects who were randomized into four arms, placebo, lanifibranor 1200mg/day (anticipated maximal therapeutic dose), lanifibranor 2400mg/day (supra-therapeutic dose), and moxifloxacin 400mg/day (positive control). The primary electrocardiogram (ECG) endpoint was monitored during the first 24hrs and on the last day of treatment.

Repeated daily administration of lanifibranor dosed up to 2 fold higher than the anticipated maximal therapeutic dose had no effect on cardiac electrical activity as shown by achieving the pre-specified primary endpoint of demonstrating no prolongation of the QT interval in healthy subjects. Lanifibranor was well tolerated at both dose levels.

**Michael Cooreman, Chief Medical Officer , stated:** *“Thorough QT studies are conducted to measure the potential risk for a drug to lead to arrhythmia. They are critical in drug development and are part of the regulatory requirements. This study confirms the safety of lanifibranor on cardiac activity previously observed in our Phase II studies.”*

### 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

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<sup>1</sup> The QT interval is the time between the Q and T waves on an electrocardiogram. It quantifies the time between the onset of depolarization of myocardial cells and their repolarization. A classic side effect of many classes of drugs is the prolongation of this QT interval.

<sup>2</sup> [Guidance for Industry E14 Clinical Evaluation of QT/QTc Interval Prolongation and Proarrhythmic Potential for Non-Antiarrhythmic Drugs \(fda.gov\)](https://www.fda.gov/oc/ohrt/guidance-for-industry-e14-clinical-evaluation-of-qt-qt-c-interval-prolongation-and-proarrhythmic-potential-for-non-antiarrhythmic-drugs)

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 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 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 cediogant (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: FR0013233012) and on the Nasdaq Global Market in the United States (ticker: IVA). [www.inventivapharma.com](http://www.inventivapharma.com).

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*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.*

*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.*