

## Inventiva selected to present the results of its NATIVE Phase IIb clinical trial with lanifibranor in NASH during a plenary session at The Liver Meeting Digital Experience™ 2020

**Daix (France), October 5, 2020** – 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 it has been selected to present the results from its 24-week Phase IIb trial evaluating lanifibranor for the treatment of NASH in an oral plenary presentation at The Liver Meeting Digital Experience™ 2020, which will be held virtually November 13-16, 2020.

Entitled "The panPPAR agonist lanifibranor induces both resolution of NASH and regression of fibrosis after 24 weeks of treatment in non-cirrhotic NASH: results of the NATIVE Phase IIb trial", the abstract will be presented by Prof. Sven Francque, M.D., Ph.D. from Antwerp University Hospital and co-principal investigator of the trial.

During this trial, lanifibranor met the primary endpoint with a statistically significant reduction of the Steatosis Activity Fibrosis score (SAF), which combines assessments of hepatocellular inflammation and ballooning, with no worsening of fibrosis in the Intention To Treat (ITT<sup>1</sup>) and Per Protocol populations (PP<sup>2</sup>). In particular, lanifibranor achieved statistically significant effects on NASH resolution with no worsening of fibrosis and improvement of fibrosis with no worsening of NASH, the US Food and Drug Administration (FDA) and European Medicine Agency (EMA) primary endpoints relevant for seeking accelerated approval during future Phase III clinical development.

### Oral presentation details

**Publication Number:** 0012

**Session Title:** Plenary: Clinical and Outcomes Discoveries

**Presentation Type:** Oral presentation, Plenary Session

**Presenting Author:** Sven Francque, M.D., Ph.D. from Antwerp University Hospital

**Session Broadcast Date and Time:** Sunday, November 15, 2020, 9:00 AM (Eastern Time)

### 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 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. 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.

### About the NATIVE Phase IIb trial

The NATIVE (Nash Trial to Validate IVA337 Efficacy) clinical trial is a 24-week randomized, double-blind, placebo-controlled Phase IIb clinical trial evaluating lanifibranor for the treatment of patients with NASH. The main purpose of the trial is to assess the efficacy of lanifibranor in improving liver inflammation and ballooning, the two

<sup>1</sup> ITT: includes all patients randomized in the trial.

<sup>2</sup> PP: includes all patients with paired biopsies and without deviation impacting efficacy assessment.

histological markers included in the definition of the regulatory endpoint of NASH resolution. To be considered for inclusion, patients were required to have: a diagnosis of NASH confirmed by liver biopsy; a cumulative score of inflammation and ballooning (as measured using the SAF scoring system) of three or four out of four, indicating the presence of moderate to severe inflammation and ballooning; a steatosis score greater than or equal to one, indicating the presence of moderate to severe steatosis; and a fibrosis score less than four, indicating the absence of cirrhosis. The primary endpoint of the trial is a reduction in the combined inflammation and ballooning score of two points compared to baseline, with no worsening fibrosis, as measured by the SAF score. Secondary endpoints include NASH resolution, improvements in each of the steatosis, inflammation, ballooning and fibrosis scores from baseline as measured using the SAF score, improvements in various other fibrosis measures, improvements in several metabolic markers, improvements in steatosis, inflammation and ballooning as measured using the NAS score (NAFLD activity score), and safety.

The trial randomized 247 patients with NASH in 71 sites in Australia, Canada, Europe, Mauritius and the United States.

### 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 earlier stage 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. Inventiva recently announced positive topline data from its Phase IIb clinical trial evaluating lanifibranor for the treatment of patients with NASH.

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. A Phase I/II clinical trial in children with MPS VI is currently under preparation following the release of positive results of the Phase IIa clinical trial in adult MPS VI patients at the end of 2019.

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 (Euronext: 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 filed with the Autorité des Marchés Financiers on June 19, 2020 under n° D.20-0551 and its amendment filed on July 10, 2020 under n° D. 20-0551-A01 as well as the half-year financial report on June 30, 2020 for additional information in relation to such factors, risks and uncertainties.*

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