

Inventiva receives positive FDA feedback to advance its lead drug candidate lanifibranor into pivotal Phase III in NASH

- ▶ FDA confirms that a single Phase III clinical trial may be adequate for submitting U.S. marketing authorization application
- ▶ Interim histology analysis may serve as the basis for seeking FDA accelerated approval
- ▶ Inventiva confirms planned initiation of pivotal Phase III clinical trial for H1 2021
- ▶ Based on positive feedback from the FDA, the Company has decided to focus its clinical efforts on the development of lanifibranor in NASH

Daix (France), November 10, 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 conclusions from its end-of-phase II meeting with the U.S. Food and Drug Administration (FDA) for its lead drug candidate lanifibranor following the publication of positive topline results from its NATIVE Phase IIb clinical trial in NASH in June 2020.

After the recent Breakthrough Therapy designation of lanifibranor in NASH, and based on the trial design presented by the Company, the FDA has indicated that Inventiva's clinical strategy to conduct a single pivotal Phase III trial may be sufficient to support the filing of a new drug application (NDA) in the U.S. The FDA also confirmed that Inventiva may request accelerated approval for lanifibranor in the event of a positive benefit-risk ratio determination based on an interim histology analysis to be conducted during the Phase III trial.

The Phase III trial preparations are progressing according to schedule and Inventiva will communicate details of the trial once it receives regulatory feedback from the European Medicines Agency (EMA), which is expected in the fourth quarter of 2020. The initiation of the Phase III trial is planned for the first half of 2021.

Given the positive feedback from the FDA, which builds on the positive topline results shown by lanifibranor in the NATIVE Phase IIb clinical trial and its designation as Breakthrough Therapy by the FDA in October, Inventiva has decided to focus its clinical efforts on the development of lanifibranor for the treatment of NASH. As part of this decision, the Company will be reviewing all available options to optimize the development of its second clinical-stage asset odiparcil for the treatment of MPS VI, and during such time, will suspend all MPS-related R&D activities. As a consequence, the Phase I/II SAFE-KIDDS (SAFETY, pharmacokinetics and pharmacodynamics, Dose escalating Study) clinical trial evaluating odiparcil in MPS VI children and the Phase IIa extension clinical trial with odiparcil in MPS VI patients who completed the prior iMPROVES Phase IIa clinical trial will not be initiated in the first half of 2021 as initially planned.

Pierre Broqua, Chief Scientific Officer and cofounder of Inventiva, commented: *"We are extremely pleased by the promising and constructive feedback from the FDA, which has given us the green light to initiate the pivotal Phase III trial with lanifibranor, our lead drug candidate for the treatment of NASH. Importantly, the FDA provided clear guidance that accelerated approval may be achievable with an interim analysis. The recent key milestones achieved with lanifibranor and the FDA feedback reinforce our confidence in its potential to become a reference treatment for NASH. With this very promising perspective ahead, we believe it is important to shift our clinical focus and concentrate on this program while ensuring the ideal development path for odiparcil in MPS. We now*

look forward to continue working closely with the EMA on finalizing lanifibranor's clinical development plan, with a view to the initiation of the Phase III trial in the first half of 2021."

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 α and PPAR δ , and a partial activation of PPAR γ . 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. The U.S. Food and Drug Administration (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 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 and obtained Breakthrough Therapy and Fast Track designation for lanifibranor in the treatment of 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. Inventiva announced positive topline data from its Phase IIa clinical trial evaluating odiparcil for the treatment of adult MPS VI patients at the end of 2019 and received FDA Fast Track designation in MPS VI for odiparcil, in October 2020.

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: FR0013233012) and on the Nasdaq Global Market in the United States (ticker: IVA). 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.

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.