

Inventiva announces the positive recommendation of the 4th and last DSMB of the Phase IIb clinical study with lanifibranor in NASH

- ▶ No safety issue reported and recommendation to continue the study without changing the protocol

Daix (France), September 10, 2019 – Inventiva (Euronext: IVA), a clinical-stage biopharmaceutical company developing oral small molecule therapies for the treatment of diseases in the areas of fibrosis, lysosomal storage disorders and oncology, today announced the positive recommendation of the fourth and last Data Safety Monitoring Board (DSMB) of the NATIVE Phase IIb clinical study evaluating lanifibranor in NASH. No safety issues were reported and, as for the first three DSMB meetings, the DSMB recommended to continue the study without changing the protocol. These conclusions are all the more significant as this safety assessment was based on the review of data from 228 patients, including 139 patients treated for the whole study period. This positive recommendation confirms once again the good safety profile of lanifibranor.

The Phase IIb clinical study NATIVE (NASH Trial to Validate IVA337 Efficacy) evaluates lanifibranor, the Company's lead product candidate, for the treatment of non-alcoholic steatohepatitis (NASH), a chronic and progressive liver disease for which there is currently no approved treatment. Following the positive conclusions of the last DSMB and the successful completion of patient recruitment in the study announced on 4 September 2019, Inventiva confirms the publication of the study results in the first semester 2020.

Pierre Broqua, Chief Scientific Officer and cofounder of Inventiva, commented: *"We are particularly satisfied with the safe profile of lanifibranor in patients with NASH. The DSMB's recommendation, as well as the FDA's decision to lift the clinical hold in place on PPAR agonists for lanifibranor, support the unique mechanism of action of our drug candidate. We look forward to the publication of the study results during the first half of 2020 and if positive, to initiate the last phase of development prior to the market launch of lanifibranor."*

About lanifibranor

Lanifibranor, Inventiva's lead product candidate, is an orally-available small molecule that acts to induce anti-fibrotic, anti-inflammatory and beneficial 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 safety and tolerability profile that has been observed in clinical trials and pre-clinical studies to date.

Inventiva is currently evaluating lanifibranor in a Phase IIb clinical trial for the treatment of non-alcoholic steatohepatitis ("NASH"), a common and progressive chronic liver disease, for which there is currently no approved therapy.

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 in the treatment of patients with non-alcoholic steatohepatitis (“NASH”). The goal of the trial is to assess the effect of lanifibranor on the improvement in liver inflammation and ballooning, which are two of the markers of the resolution of NASH. To be considered for inclusion, patients must have: a diagnosis of NASH confirmed by liver biopsy; a cumulative score of inflammation and ballooning (as measured using the steatosis, activity and fibrosis, or “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; 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, without worsening fibrosis. Secondary endpoints include NASH resolution, improvements of the steatosis, inflammation, ballooning and fibrosis scores from baseline as measured using the NAS and SAF scores, improvements of other fibrosis measures, improvements in several metabolic markers and safety.

The trial has randomized 247 patients with NASH at more than 70 sites in Australia, Canada, Europe, Mauritius and the United States. Results of the trial are expected in the first half of 2020.

About Inventiva

Inventiva is a clinical-stage biopharmaceutical company focused on the development of oral small molecule therapies for the treatment of diseases with significant unmet medical needs in the areas of fibrosis, lysosomal storage disorders and oncology.

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 – lanifibranor and odiparil – in non-alcoholic steatohepatitis (“NASH”) and mucopolysaccharidosis (“MPS”), respectively, 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. Inventiva is currently evaluating lanifibranor in a Phase IIb clinical trial for the treatment of this disease for which there are currently no approved therapies.

Inventiva is also developing odiparil, a second clinical-stage asset, for the treatment of patients with MPS, a group of rare genetic disorders. The Company is currently investigating odiparil in a Phase IIa clinical trial for the treatment of patients with the MPS VI subtype.

In parallel, Inventiva is in the process of selecting an oncology development candidate for its Hippo signalling pathway program. The Company has established two strategic partnerships with AbbVie and Boehringer Ingelheim in the areas of autoimmune diseases and idiopathic pulmonary fibrosis (“IPF”) respectively. AbbVie has started the clinical development phase of ABBV-157, a drug candidate for the treatment of moderate to severe psoriasis resulting from its collaboration with Inventiva. Both collaborations entitle 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 partnerships.

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, around 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). www.inventivapharma.com

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Please refer to the “Document de référence” filed with the Autorité des Marchés Financiers on April 12, 2019 under n° R.19-006 for additional information in relation to such factors, risks and uncertainties.

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