

## Inventiva announces completion of patient visits for its Phase IIb clinical study with lanifibranor in NASH

- ▶ Last patient last visit took place in the United States on March 16, 2020
- ▶ Publication of study head-line results expected for June 2020

**Daix (France), March 17, 2020** – 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 last visit of the last patient out of the 247 patients enrolled in its Phase IIb clinical study with lanifibranor in NASH. The last patient biopsy was performed in February and the last safety visit took place in the United States on March 16, 2020. All biopsies have been analysed by the central hepatologist and the publication of the study head-line results is planned in June 2020, in line with Company's expectations.

The NATIVE (**NA**sh Trial to **VA**lidate IVA337 Efficacy) trial is a 24-week randomized, double-blind, placebo-controlled Phase IIb clinical study evaluating lanifibranor in the treatment of patients with non-alcoholic steatohepatitis (NASH). The main purpose of the study is to assess the efficacy of lanifibranor in improving liver inflammation and ballooning, the two histological markers included in the definition of the regulatory endpoint of NASH resolution. Secondary endpoints of the study also include NASH resolution and improvement in each of the steatosis, inflammation, ballooning and fibrosis scores from baseline.

Throughout the study, the safety profile of lanifibranor has been regularly assessed by an external, independent Data Safety Monitoring Board (DSMB). Four meetings of the DSMB took place between June 2018 and September 2019 and as no safety issues were reported, the DSMB repeatedly recommended the continuation of the study without any modification of the protocol, thus confirming the good safety profile of lanifibranor.

**Prof. Sven Francque, M.D., Ph.D. from the Antwerp University Hospital and co-principal investigator of the study, said:** *"With this last milestone before the publication of the study results achieved on schedule, I am very delighted to see that the trial is progressing as planned. The commitment and the quality of the work delivered by the clinicians and centers involved in the trial have been outstanding and I am sure this will result in high quality data. I am eager to see the results of this trial and to continue working on the development of lanifibranor."*

**Prof. Manal Abdelmalek, M.D., M.P.H. from Duke University and co-principal investigator of the study with Prof. Sven Francque, added:** *"I am very pleased to have completed this last patient visit and I am proud of our team who has been able to accelerate patient enrollment in the United States. The profile of lanifibranor, as a drug candidate that could prove beneficial to NASH patients worldwide, is strong and compelling. I look forward to the successful completion of this study and the upcoming publication of the study head-line results."*

**Pierre Broqua, CSO and cofounder of Inventiva, stated:** *"Backed by the solid design and roll-out of the NATIVE clinical study and the preclinical and clinical results generated by lanifibranor so far, we are convinced that its profile as a pan-PPAR agonist and its ability to combine the beneficial effects of all three PPAR isoforms constitute a clear advantage in the treatment of NASH. These characteristics give our leading drug candidate a differentiated mechanism of action that should enable it to meet the efficacy endpoints of our Phase IIb clinical*

study. We are looking forward to publishing the head-line results in the next few months, which, if positive, will support the launch of the pivotal Phase III study with lanifibranor.”

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### 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 $\alpha$  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 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 main purpose of the study is to assess the efficacy of lanifibranor in improving liver inflammation and ballooning, the two histological markers included in the definition of the regulatory endpoint of NASH resolution. 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, 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, without worsening fibrosis. Secondary endpoints include NASH resolution, improvements in each of the steatosis, inflammation, ballooning and fibrosis scores from baseline as measured using the SAF score, and also in various other fibrosis measures, in several metabolic markers, as well as in steatosis, inflammation and ballooning as measured using the “NAS” score, and safety.

The trial 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 June 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 significant 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. A Phase I/II clinical trial in children with MPS VI is currently under preparation following the positive results of the Phase IIa clinical trial in adult MPS VI patients published 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 partnership with AbbVie in the area of autoimmune diseases. 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. This collaboration entitles Inventiva to receive milestone payments upon the achievement of pre-clinical, clinical, regulatory and commercial objectives, in addition to royalties on any approved products resulting from this partnership.

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 chemical 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: FRO013233012). [www.inventivapharma.com](http://www.inventivapharma.com)

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