

# Inventiva to provide an update on the NATIVE Phase IIb clinical trial in NASH during a Key Opinion Leader webcast

Event to take place on May 4, 2020 at 10:00 am (ET) / 4:00 pm (CET)

Daix (France), April 21, 2020 – Inventiva (Euronext: IVA), a clinical-stage biopharmaceutical company developing 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 will host a webcast presentation with two Key Opinion Leaders on May 4, 2020 to provide an update on its Phase IIb NATIVE (NAsh Trial to Validate IVA337 Efficacy) clinical trial evaluating lanifibranor for the treatment of NASH ahead of the release of headline results, which is expected in June 2020.

With the participation of Prof. Sven Francque, M.D., Antwerp University Hospital, co-principal investigator of the NATIVE clinical trial, and Prof. Pierre Bedossa, M.D., Paris-Diderot University, the central pathologist in charge of the biopsy analyses of the NATIVE clinical trial, the Company will discuss the trial design and present the characteristics of the patient population. At this stage, the trial remains blinded, in line with the protocol.

During this event, which had initially been scheduled to take place during the International Liver Congress 2020 (European Association for the Study of the Liver), Inventiva will explain the methodology used for the analysis of patient biopsies in the NATIVE clinical trial, and compare the different screening approaches currently used in NASH clinical trials, in particular the Steatosis, Activity, Fibrosis ("SAF") and NAFLD Activity Score ("NAS") scoring systems.

**Pierre Broqua, CSO** and cofounder of Inventiva, said: "After the analysis of all biopsies in the NATIVE clinical trial announced in mid-March, this webcast represents the last event before the expected publication of the trial's headline results in June 2020. Prior to the clinical data release, we would like to review the different aspects of the trial in detail and we are delighted to benefit, on this occasion, from the participation of Prof. Sven Francque and Prof. Pierre Bedossa, two highly recognized experts in the NASH field. In particular, we will focus on how the trial design and our innovative screening strategy based on the SAF score enabled us to meet our patient recruitment objectives, including a high percentage of patients with severe steatohepatitis associated with advanced fibrosis."

The event details are as follows:

Date: Monday, May 4, 2020

Time: 10:00 am - 11:30 am (ET) / 4:00 pm - 5:30 pm (CET)

**Speakers:** Prof. Pierre Bedossa, M.D., Paris-Diderot University, pathologist in charge of the

biopsy analyses of the NATIVE clinical trial

Pierre Broqua, CSO and cofounder of Inventiva

Prof. Sven Francque, M.D., Antwerp University Hospital, co-principal investigator of

the NATIVE clinical trial

Connection details: Option #1 – Webcast: https://edge.media-server.com/mmc/p/dmwekswt

Option #2 - Conference call:

Numbers:

France: +33 (0) 1 70 70 82 21 Belgium: +32 (0) 2 400 3439



Germany: +49 (0) 69 2443 7403 Netherlands: +31 (0) 20 715 7566 Switzerland: +41 (0) 44 580 6084 United Kingdom: +44 (0) 203 009 5709

United States: +1 646-787-1226

Access code: 5267504

The presentation document and the link to the webcast will also be available on Inventiva's website in the "Investors — Investor Presentations" section. A replay of the event will be available at: <a href="http://inventivapharma.com/investors/investor-presentations/">http://inventivapharma.com/investors/investor-presentations/</a>.

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#### **About lanifibranor**

Lanifibranor, Inventiva's lead product candidate, is an orally-available small molecule that acts to induce antifibrotic, 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 $\alpha$ , and a partial activation of PPAR $\alpha$ . 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 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 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 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, 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, improvements in various other fibrosis measures, improvements in several metabolic markers, improvements 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 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. 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 odiparcil, a second clinical stage asset, for the treatment of patients with MPS, a group of rare genetic disorders. A Phase Ib/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 50 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). <a href="https://www.inventivapharma.com">www.inventivapharma.com</a>

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### **Important Notice**

This press release contains forward-looking statements, forecasts and estimates with respect to Inventiva's clinical trials, clinical trial data releases, clinical development plans, , and anticipated future activities of Inventiva. Certain of these statements, forecasts and estimates can be recognized by the use of words such as, without limitation, "believes", "anticipates", "expects", "intends", "plans", "seeks", "estimates", "may", "will" and "continue" and similar expressions. Such statements are not historical facts but rather are statements of future expectations and other forward-looking statements that are based on management's beliefs. These statements reflect such views and assumptions prevailing as of the date of the statements and involve known and unknown risks and uncertainties that could cause future results, performance or future events to differ materially from those



expressed or implied in such statements. Actual events are difficult to predict and may depend upon factors that are beyond Inventiva's control. There can be no guarantees with respect to pipeline product candidates that the clinical trial results will be available on their anticipated timeline, that future clinical trials will be initiated as anticipated, or that candidates will receive the necessary regulatory approvals. Therefore, actual results may turn out to be materially different from the anticipated future results, performance or achievements expressed or implied by such statements, forecasts and estimates. Given these uncertainties, no representations are made as to the accuracy or fairness of such forward-looking statements, forecasts and estimates. Furthermore, forward-looking statements, forecasts are cautioned not to place undue reliance on any of these forward-looking statements.

Please refer to the Universal Reference Document filed with the Autorité des Marchés Financiers on February 7, 2020 under n° D.20-0038 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.