

Inventiva announces the presentation of five scientific abstracts at the AASLD The Liver Meeting<sup>™</sup> 2021

- Four poster presentations add to the evidence of the beneficial effects of lanifibranor therapy on key components of NASH, following further sub-analyses of Inventiva's NATIVE Phase IIb clinical trial results
- The fifth poster presentation demonstrates that lanifibranor improves NASH, fibrosis and diastolic dysfunction in a hamster model of diet-induced NASH and diastolic dysfunction

Daix (France), Long Island City (New York, United States), October 18, 2021 – 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 needs, today announced that five scientific abstracts have been selected for poster presentations during the upcoming The Liver Meeting<sup>™</sup> 2021, organized by the American Association for the Study of Liver Diseases (AASLD) on November 12-15, 2021.

The first abstract focuses on the improvement of insulin resistance and the reversal to normoglycemia in patients with non-cirrhotic NASH and prediabetes treated with lanifibranor. Prediabetes, defined by fasting glucose levels, is a risk factor for cardiovascular disease (CVD). Based on Inventiva's NATIVE Phase IIb clinical trial evaluating lanifibranor in NASH, the authors show that markers of glucose metabolism improved in patients with non-cirrhotic NASH and prediabetes during treatment with lanifibranor.

The second abstract demonstrates the beneficial effect of lanifibranor on the reduction of hepatic steatosis and shows a correlation with markers of lipid and glucose metabolism. The authors explain that, during the NATIVE Phase IIb clinical trial, lanifibranor therapy induced a decrease of steatosis, as measured by the Controlled Attenuation Parameter (CAP, Fibroscan) method, consistent with the decrease of steatosis observed with histological grading.

The third abstract highlights the correlation between NASH resolution and fibrosis improvement following lanifibranor treatment. The results from the NATIVE Phase IIb clinical trial show that, following treatment at both doses of lanifibranor (800mg/daily and 1200mg/daily), NASH resolution responders were significantly more likely to also be fibrosis improvers. Such correlation was also observed between ballooning improvement and fibrosis improvement.

The fourth abstract focuses on the positive effect of lanifibranor therapy in reducing Liver Sinusoidal Endothelial Cell (LSEC) capillarization. Based on the results of the NATIVE Phase IIb clinical trial, the authors analysed the change in capillarization (measured by CD34 immunostaining) of LSEC in patients with NASH and an activity >3 according to the Steatosis Activity Fibrosis (SAF) score<sup>1</sup>. CD34 staining increased with inflammation grade and fibrosis progression. Lanifibranor showed a dose dependent reduction of CD34 staining which reached significance in the periportal area.

<sup>&</sup>lt;sup>1</sup> The SAF score combines assessments of hepatocellular inflammation and ballooning.



The fifth abstract demonstrates that lanifibranor improves NASH, fibrosis and diastolic dysfunction in a hamster model of diet-induced NASH and diastolic dysfunction. In a non-clinical study conducted in a hamster model of NASH and diastolic dysfunction induced by a diet rich in fat, cholesterol and fructose, the authors evaluated the effect of pan-PPAR agonist lanifibranor. The results show that lanifibranor significantly reduced lipids metabolism markers and reversed steatosis, inflammation and fibrosis while significantly improving diastolic dysfunction. This new data further supports the potential development of lanifibranor as a treatment for NASH patients with high risk of cardiovascular diseases.

These abstracts will be available for viewing by attendees on the AASLD website and will also be featured in the October supplement of the scientific journal *Hepatology*.

The details of the five poster presentations are as follows:

#### Abstract #1:

Abstract title:	"Lanifibranor reverses fasting glucose levels to normoglycemia in prediabetic patients with nonalcoholic steatohepatitis (NASH)"
Publication number:	1920
Session title:	NAFLD and NASH: Therapeutics - Pharmacologic and Other
Author:	Dr. Michael Cooreman, Chief Medical Officer of Inventiva

## Abstract #2:

Abstract title:	"Lanifibranor treatment improves hepatic steatosis in patients with NASH, evaluated by histological grading and Controlled Attenuation Parameter (CAP)"
Publication number:	1921
Session title:	NAFLD and NASH: Therapeutics - Pharmacologic and Other
Author:	Dr. Michael Cooreman, Chief Medical Officer of Inventiva

## Abstract #3:

Abstract title:	"Treatment response to the PAN-PPAR agonist lanifibranor in the NATIVE study: NASH resolution and fibrosis improvement are correlated"
Publication number:	1938
Session title:	NAFLD and NASH: Therapeutics - Pharmacologic and Other
Author:	Prof. Arun Sanyal, M.D., Virginia Commonwealth University and co-principal investigator of Inventiva's NATiV3 Phase III clinical trial

#### Abstract #4:

Abstract title:	"Liver Sinusoidal Endothelial Cell (LSEC) capillarization in NASH and its evolution following lanifibranor treatment: an exploratory study of the NATIVE clinical trial"
Publication number:	1874
Session title:	NAFLD and NASH: Experimental: Clinical
Author:	Prof. Pierre-Emmanuel Rautou, MD, PhD, Hopital Beaujon



# Abstract #5:

Abstract title:	"Lanifibranor improves NASH, fibrosis and diastolic dysfunction in a hamster preclinical model of diet induced NASH"
Publication number:	1919
Session title:	NAFLD and NASH: Therapeutics - Pharmacologic and Other
Presentation type:	Poster presentation
Author:	Guillaume Wettstein, Head of Pharmacology of Inventiva

# About the American Association for the Study of Liver Diseases (AASLD)<sup>2</sup>

AASLD is the leading organization of scientists and health care professionals committed to preventing and curing liver disease. AASLD fosters research that leads to improved treatment options for millions of liver disease patients. We advance the science and practice of hepatology through educational conferences, training programs, professional publications, and partnerships with government agencies and sister societies.

# **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 $\delta$ , 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 for the treatment of NASH. 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 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 preclinical 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. In 2020, Inventiva announced positive topline data from its Phase IIb clinical trial evaluating lanifibranor for the treatment of patients with NASH and obtained both FDA Breakthrough Therapy and Fast Track designation for lanifibranor in the treatment of NASH. Lanifibranor is currently being evaluated in a pivotal Phase III clinical trial.

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

<sup>&</sup>lt;sup>2</sup> <u>https://www.aasld.org/</u>



evaluating odiparcil for the treatment of adult MPS VI patients in 2019 and received both FDA Fast Track and Rare Paediatric Disease designation for odiparcil in MPS VI.

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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## **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. 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, due to a number of factors, including that Inventiva is a clinical-stage company with no approved products and no historical product revenues, Inventiva has incurred significant losses since inception, Inventiva has a limited operating history and has never generated any revenue from product sales, Inventiva will require additional capital to finance its operations, Inventiva's future success is dependent on the successful clinical development, regulatory approval and subsequent commercialization of current and any future product candidates, preclinical studies or earlier clinical trials are not necessarily predictive of future results and the results of Inventiva's clinical trials may not support Inventiva's product candidate claims, Inventiva may encounter substantial delays in its clinical trials or Inventiva may fail to demonstrate safety and efficacy to the



satisfaction of applicable regulatory authorities, enrollment and retention of patients in clinical trials is an expensive and time-consuming process and could be made more difficult or rendered impossible by multiple factors outside Inventiva's control, Inventiva's product candidates may cause adverse drug reactions or have other properties that could delay or prevent their regulatory approval, or limit their commercial potential, Inventiva faces substantial competition and Inventiva's business, and preclinical studies and clinical development programs and timelines, its financial condition and results of operations could be materially and adversely affected by the current COVID-19 pandemic. Given these risks and uncertainties, no representations are made as to the accuracy or fairness of such forward-looking statements, forecasts and estimates. Furthermore, forward-looking statements, forecasts and estimates are cautioned not to place undue reliance on any of these forward-looking statements.

Please refer to the Universal Registration Document for the year ended December 31, 2020 filed with the Autorité des Marchés Financiers on March 15, 2021, the Annual Report on Form 20-F for the year ended December 31, 2020 filed with the Securities and Exchange Commission on March 15, 2021 as well as the half-year financial report for the six months ended June 30, 2021 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 forwardlooking statements referred to above. Consequently, Inventiva accepts no liability for any consequences arising from the use of any of the above statements.