

# Inventiva announces collaboration on non-invasive biomarkers to identify patients responding to lanifibranor with regards to NASH resolution and fibrosis improvement

- ► The Company will collaborate with Professor Jérôme Boursier, M.D., Ph.D, a renowned scientist in the field of non-invasive diagnosis of liver lesions in chronic liver diseases
- ► The collaboration aims at developing one or several biomarkers or a composite biomarker score to identify patients responding to lanifibranor with regards to NASH resolution and fibrosis improvement
- ► The biomarker data from the NATIVE Phase IIb clinical trial with lanifibranor in NASH will be used as a first validation dataset and the lanifibranor biomarker signature would then be validated during upcoming NATIV3 Phase III clinical trial

Daix (France), February 25, 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 need, today announced a collaboration in the field of NASH biomarkers with Professor Jérôme Boursier, M.D., Ph.D, Professor of Medicine at the Faculty of Medicine of Angers University and renowned scientist in the area of non-invasive diagnosis of liver lesions in chronic liver diseases.

The objective of the collaboration is to develop one or several biomarkers or a composite biomarker score to identify patients responding to lanifibranor with regards to NASH resolution and fibrosis improvement. More specifically, Professor Jérôme Boursier, M.D., Ph.D, and his team from the HIFIH¹ Laboratory (UPRES EA3859, Angers University) will use a multivariate statistical approach to finding a biomarker signature of lanifibranor in NASH treatment.

As part of this collaboration, the database from Inventiva's NATIVE Phase IIb clinical trial evaluating lanifibranor for the treatment of NASH and containing a list of around 80 biomarkers will be used as a first validation dataset. The selected biomarker(s) or biomarker composite score would then be validated during the upcoming NATIV3 (NASH lanifibranor Phase III trial) Phase III clinical trial with lanifibranor in NASH, the initiation of which is planned for the first half of 2021. As a reminder, several analyses of biomarkers and other non-invasive tests based on the results from the NATIVE Phase IIb trial had shown promising treatment effects of lanifibranor versus placebo and were presented during a webcast event from The Liver Meeting Digital Experience™ 2020 on November 16, 2020.²

**Pierre Broqua, CSO and cofounder of Inventiva, commented**: "With an increasing number of patients developing NASH-related end-stage liver disease and pharmacological treatments on the horizon, there is a pressing need to develop NASH biomarkers for prognostication, patient selection and treatment monitoring. We are therefore very excited to start this collaboration with Professor Jérôme Boursier and his team, who have been extensively involved in the development of non-invasive tests to diagnose NASH patients over the past years. Developing a non-invasive

<sup>&</sup>lt;sup>1</sup> HIFIH: "Hémodynamique, Interaction Fibrose, Invasivité Tumorales Hépatiques" – Hemodynamics, Fibrosis Interaction and Hepatic Tumor Invasiveness.

<sup>&</sup>lt;sup>2</sup> A replay of the presentation is accessible via the following link: <a href="https://edge.media-server.com/mmc/p/uy4bgbir.">https://edge.media-server.com/mmc/p/uy4bgbir.</a>



biomarker signature to identify responders to lanifibranor is totally in line with our strategy to make our lead drug candidate a reference treatment for NASH patients."

Jérôme Boursier, M.D., Ph.D., Professor of Medicine at the Faculty of Medicine of Angers University, stated: "The need to develop reliable NASH biomarkers is both clear and urgent as the utility of liver biopsy, the only diagnostic approach currently available, is limited due to its invasive nature, poor patient acceptability and sampling variability. So we are very much looking forward to working with Inventiva on lanifibranor, a drug candidate that has shown very promising results in the field of NASH. Given the efficacy shown by lanifibranor during the NATIVE Phase IIb trial and the promising biomarker dataset available, we are confident that we will be able to meet our objective to develop one or several robust biomarkers or composite biomarker score."

## Biography - Jérôme Boursier

Jérôme Boursier, M.D., Ph.D., is Professor of Medicine at the Faculty of Medicine of Angers University, France. His main field of research covers the non-invasive diagnosis of liver lesions in chronic liver diseases, especially Non-Alcoholic Fatty Liver Disease (NAFLD). In parallel, Professor Boursier heads the HIFIH Laboratory (UPRES EA3859, SFR 4208) at Angers University and the Department of Hepato-Gastroenterology and Digestive Oncology at Angers University Hospital. Graduated from the Faculty of Medicine of Angers University, his Ph.D work focused on methodology to improve the accuracy of the non-invasive diagnosis of liver fibrosis in chronic hepatitis C. In the context of a research fellowship at the Anna Mae Diehl Lab of Duke University, Durham, United States, Professor Boursier investigated in the area of the gut microbiota and NAFLD. He currently leads many studies about the diagnosis, screening and prognosis assessment in NAFLD.

### **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. In July 2020, Inventiva 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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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 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 undesirable side effects 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, 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 only speak as of the date of this press release. Readers are cautioned not to place undue reliance on any of these forward-looking statements.



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.