Inventiva Announces a U.S. Phase II Investigator-Initiated Study with Lanifibranor on Non-Alcoholic Fatty Liver Disease in Patients with Type 2 Diabetes

Dr. Kenneth Cusi of the University of Florida to be principal investigator

Trial in 64 patients to begin after the FDA has approved lanifibranor IND

Daix (France), April 3rd, 2018 – Inventiva, a biopharmaceutical company developing innovative therapies in nonalcoholic steatohepatitis (NASH), systemic sclerosis (SSc) and mucopolysaccharidosis (MPS), today announced that Dr. Kenneth Cusi, Chief of the Division of Endocrinology, Diabetes & Metabolism in the Department of Medicine at the University of Florida, Gainesville, has selected lanifibranor for a Phase II investigator-initiated clinical trial. The trial's objective is to evaluate the efficacy and safety of lanifibranor on intrahepatic triglycerides and hepatic insulin sensitivity in type 2 diabetic patients with nonalcoholic fatty liver disease (NAFLD). A positive result would further reinforce lanifibranor as the ideal drug for NAFLD and NASH patients with type 2 diabetes (T2DM).

Lanifibranor is a new generation panPPAR agonist that activates the alpha, gamma and delta isoforms of the peroxisome proliferator-activated receptors (PPARs). Lanifibranor selection for this study was motivated by this unique mechanism of action that can potentially address all key features of NAFLD and NASH: improvement of insulin-sensitivity, steatosis reduction, anti-inflammatory activity and reduction of fibrosis. In parallel to this investigator-initiated study, Inventiva is currently conducting two lanifibranor Phase IIb clinical trials in NASH and SSc. The Company has been granted orphan drug designation for lanifibranor by the U.S. Food and Drug Administration (FDA) and the European Medicines Agency (EMA) in SSc.

"PPARs are clinically validated targets to treat patients suffering from NAFLD or NASH. Lanifibranor with its moderate and balanced panPPAR profile and its gamma activity, is a very promising candidate adressing most if not all the components of NASH" Dr. Cusi said. *"We anticipate this profile will translate well into type 2 diabetic patients affected by NAFLD or NASH and are confident in the success of this trial."*

Jean-Louis Abitbol, MD, MSC, Chief Medical Officer of Inventiva, said: *"We are delighted that Dr. Cusi, a renowned expert in the PPAR field and world-class clinician has selected lanifibranor for this study that will provide us with additional supportive data for our regulatory filings of lanifibranor with U.S. and European regulators."*

Pierre Broqua, Chief Scientific Officer and a co-founder of Inventiva, added: *"We are extremely excited by this collaboration with Dr Cusi. This study meets several of our strategic objectives with a contained financial investment, including opening an IND[1], initiating a study in the US in a population likely to benefit from lanifibranor treatment and enlarge the clinical data package for future interactions with FDA."*

The trial conducted by Dr. Cusi is expected to enroll 64 patients treated for a 24-week period with a single daily dose of lanifibranor (800mg/day) and 10 subjects in a healthy, non-obese control group. The study's overall

[1] IND: Investigational New Drug

objective is to measure the metabolic effects of lanifibranor, and its potential efficacy on steatosis in T2DM patients with NAFLD. Additionally this study will detect lanifibranor impact on fibrosis using the most recent imaging technology. The main endpoints are a decrease of liver steatosis assessed by state of the art imaging, including H-MRS (Proton Magnetic Resonance Spectroscopy), evidence of metabolic improvements in insulin resistance (glucose clamp, HBA1c), de novo lipogenesis, free fatty acids, lipids and safety. The trial should begin in Q2/Q3 2018 depending on FDA approval of lanifibranor IND filing.

Webcast

A **webcast on this study** will be held in English **on April 5th, 2018 at 6:15pm CEST**.
To join, please use the code 5361123 after dialing one of the following numbers:

France: +33 (0)1 76 77 22 57
Belgium: +32 (0)2 400 6926
Denmark: +45 35 15 81 21
Germany: +49 (0)69 2222 2018
Netherlands: +31 (0)20 703 8261
Switzerland: +41 (0)22 567 5750
United Kingdom: +44 (0)330 336 9411
United States: +1 323-794-2093

The presentation accompanying this webcast will be available on Inventiva's website at 6:15pm CEST on the same day in the "Investor" – "Documentation" – "Investor presentations" section and can be followed live at the same time at: https://edge.media-server.com/m6/p/rg74y7wv

A replay of the webcast and presentation will be available from 9:30pm CEST onwards on the same day at: https://edge.media-server.com/m6/p/rg74y7wv

About Inventiva: www.inventivapharma.com

Inventiva is a biopharmaceutical company specialized in the development of drugs interacting with nuclear receptors, transcription factors and epigenetic modulators. Inventiva's research engine opens up novel breakthrough therapies against fibrotic diseases, cancers and orphan diseases with substantial unmet medical needs.

Lanifibranor, its lead product, is an anti-fibrotic treatment acting on the three alpha, gamma and delta PPARs (peroxisome proliferator-activated receptors), which play key roles in controlling the fibrotic process. Its anti-fibrotic action targets two initial indications with substantial unmet medical need: NASH, a severe and increasingly prevalent liver disease already affecting over 30 million people in the United States, and systemic sclerosis, a disease with a very high mortality rate and for which there is no approved treatment to date.

Inventiva is also developing in parallel, a second clinical product, Odiparcil (formerly IVA336), a treatment for several forms of mucopolysaccharidosis where dermatan and/or chondroïtin sulfates GAGs accumulate: MPS I or Hurler/Scheie syndromes, MPS II or Hunter syndrome, MPS IVa or Morquio syndrome, MPS VI or Maroteaux-Lamy syndrome and MPS VII or Sly syndrome. Inventiva is also developing a preclinical stage oncology portfolio.

Inventiva benefits from partnerships with world-leading research entities such as the Institut Curie. Two strategic R&D partnerships have also been established with AbbVie and Boehringer Ingelheim, making Inventiva eligible for preclinical, clinical, regulatory and commercial milestone payments, in addition to royalties on the products resulting from the partnerships.

Inventiva employs over 100 highly qualified employees and owns state-of-the-art R&D facilities near Dijon, acquired from the international pharmaceutical group Abbott. The Company owns, a proprietary chemical library of over 240,000 molecules as well as integrated biology, chemistry, ADME and pharmacology platforms.

About Dr. Cusi

Dr. Cusi is the principal investigator of a number of ongoing clinical research projects. His grants focus on cutting-edge research in adult endocrinology, diabetes and metabolism, both on clinical and basic research aspects related to the role of obesity and lipotoxicity in the development of Type 2 diabetes and its complications, in particular, the pathogenesis of NAFLD. He has published in the main journals in the fields of obesity, diabetes and liver disease. Dr. Cusi is a nationally and internationally recognized investigator and speaker on the impact of NAFLD in humans, including a frequently cited paper in the New England Journal of Medicine on the first effective pharmacological agent for the treatment of NAFLD, a common and potentially serious complication of obesity and T2DM that may lead to severe liver damage. He is a reviewer in numerous scientific journals. Dr. Cusi is also co-founder of Children in Need, Inc., an organization created to assist disadvantaged children and their families in third world countries, with emphasis on hospitals and schools in Southern Africa.

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This press release contains forward-looking statements, forecasts and estimates with respect to the clinical development plans, business and regulatory strategy, and anticipated future performance of Inventiva and of the market in which it operates. 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 candidates will receive the necessary regulatory approvals or that they will prove to be commercially successful. 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 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 "Document de référence" filed with the Autorité des Marchés Financiers on April 26, 2017 under n° R.17-025 for additional information in relation to such factors, risks and uncertainties.

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.