FDA Approval of an Investigator Initiated IND Application to Conduct Phase II Study of Lanifibranor in Type 2 Diabetic Patients with Non-Alcoholic Fatty Liver Disease

- Study to enroll first patient in the third quarter 2018 with topline results expected early 2020
- FDA approval is a positive signal for SSc and NASH IND applications

Daix (France) June 20, 2018 – Inventiva S.A. ("Inventiva" or the "Company"), a biopharmaceutical company developing innovative therapies in nonalcoholic steatohepatitis (NASH), systemic sclerosis (SSc) and mucopolysaccharidosis (MPS), today announced that the U.S. Food and Drug Administration (FDA) has accepted the investigator initiated Investigational New Drug (IND) application providing clearance to proceed with the Phase II study of lanifibranor in type 2 diabetic patients with nonalcoholic fatty liver disease (NAFLD). This FDA approval is also a positive signal for the planned Company IND applications in SSc and NASH.

The trial to be conducted by Dr. Kenneth Cusi, Chief of the Division of Endocrinology, Diabetes & Metabolism in the Department of Medicine at the University of Florida, Gainesville, is expected to enroll 64 patients treated for a 24-week period with a single daily dose of lanifibranor (800 mg/day) or placebo and 10 subjects in a healthy, non-obese control group. The study's overall objective is to measure the metabolic improvements induced by lanifibranor, and its effect on steatosis in type 2 diabetic patients with NAFLD. Additionally, this study will detect lanifibranor's impact on fibrosis using the most recent imaging and biomarker technology. Its main endpoints are a decrease of liver steatosis assessed by state-of-the-art imaging, including H-MRS (Proton Magnetic Resonance Spectroscopy), a decrease of insulin resistance (glucose clamp, HBA1c), a decrease in de novo lipogenesis, and safety. The first patient is expected to be enrolled in the third quarter of 2018 and topline results are expected beginning of 2020.

"With its unique pan-PPAR profile, lanifibranor has shown very good safety features, relevant efficacy data in NASH preclinical models as well as positive metabolic effects in a Phase IIa study in diabetic patients," Dr. Cusi said. *"We anticipate the results of this study to translate well to diabetic patients with NAFLD or NASH and look forward to demonstrating that lanifibranor could become a very valuable drug for these patients."*

Jean-Louis Abitbol, MD, MSC, Chief Medical Officer of Inventiva, added: *"We are delighted that the FDA has allowed Dr Cusi and his team to proceed with this exciting metabolic and imaging study and we very much look forward to the enrollement of US patients as these results will provide additional supporting data for our regulatory filings with US and European regulators."*

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 a second clinical program with odiparcil (IVA 336) for the treatment of patients with mucopolysaccaridosis type VI (or Maroteaux-Lamy syndrome), a rare and severe gene disease affecting children. Odiparcil has also the potential to address other MPS types, characterized by the accumulation of chondroitin or dermatan sulfate (MPS I or Hurler/Sheie syndrome, MPS II or Hunter syndrome, MPS IVa or Morqio syndrome and MPS VII or Sly syndrome). Inventiva is also developing a portfolio of early research projects in the field of oncology.

Inventiva benefits from partnerships with world-leading research entities such as the Institut Curie in the field of oncology. Two strategic partnerships have also been established with world-class major pharmaceutical companies AbbVie and Boehringer Ingelheim in the fields of autoimmune diseases (specifically in psoriasis) and fibrosis respectively. These partnerships provide milestone payments to Inventiva upon the achievement of pre-clinical, clinical, regulatory and commercial milestones, 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.

Contacts

Inventiva
Frédéric Cren
Chief Executive Officer
info@inventivapharma.com
+33 3 80 44 75 00

Brunswick
Julien Trosdorf / Yannick Tetzlaff
Media relations
inventiva@brunswickgroup.com
+33 1 53 96 83 83

LifeSci Advisors
Chris Maggos
Investor relations
chris@lifesciadvisors.com
+41 79 367 6254

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Please refer to the "Document de référence" filed with the Autorité des Marchés Financiers on April 13, 2018 under n° R.18-013 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.