

Inventiva Announces Last Visit by Last Patient in its Phase IIb SSc Trial and Second Positive DSMB Review in its Phase IIb NASH Trial with Lanifibranor

- ▶ Top-line results of the Phase IIb systemic sclerosis (SSc) trial are expected for early 2019
- ▶ Second NASH DSMB recommends to continue the trial with lanifibranor without changing the protocol

Daix (France), October 15, 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 the last visit by the last patient in its Phase IIb FASST (*For A Systemic Sclerosis Treatment*) trial as well as the second positive review of the Data Safety Monitoring Board (DSMB) in its Phase IIb NATIVE (*NASH Trial to Validate IVA337 Efficacy*) trial, both conducted with lanifibranor.

The last visit of the last patient of the 12-month FASST study took place on October 12 and data-base lock is planned for early January 2019. With this positive background, the Company confirmed that it expects to announce top-line results of the study in early 2019 as previously announced.

“SSc is a debilitating disease with no disease-modifying treatments approved so far where lanifibranor mechanism of action could prove beneficial for our patients. Given that all three DSMB meetings regarding the FASST trial recommended to pursue with the study without any modifications to the protocol, we are very eager to see the results of this study,” said Yannick Allanore, co-principal investigator of the FASST trial and professor of rheumatology at the Hôpital Cochin in Paris.

Professor Christopher Denton, co-principal investigator of the FASST trial and professor at the University College London, added: *“The FASST trial is a long-term study in SSc patients that will evaluate clinical endpoints highly relevant to clinicians, patients and health authorities. Positive results in this study would therefore be very supportive to the development of lanifibranor as a treatment in this very severe disease.”*

Additionally, the DSMB from the Company’s NATIVE trial in NASH patients held its second meeting. Out of the 101 patients randomized so far, the DSMB had access to the data of 95 patients of which 36 had completed the 6 month treatment period of the study. Based on its analysis, the DSMB recommended the study to continue without any modification of the protocol.

Pierre Broqua, CSO and cofounder of Inventiva, stated: *“We are very satisfied with the progress of the FASST study and excited by the prospect of publishing the head-line results early next year. The results of the second DSMB meeting regarding our NATIVE study are also very encouraging and headline results are expected for the first half of 2020.”*

About the Phase IIb FASST trial

The Phase IIb FASST trial is a one-year randomized double-blind study designed to measure the effect of lanifibranor on the progression of SSc. Patients receive either lanifibranor or placebo according to the study protocol, approved by the European Medicines Agency (EMA). The primary endpoint is change in the Modified Rodnan Skin Score (MRSS), which is a measure of disease progression accepted by both the Food and Drug

Administration (FDA) and EMA. Inclusion criteria are based on a MRSS between 10 and 25 points, and diffuse SSc diagnosed from less than 3 years. Patients are allowed to continue their ongoing treatments, including immunosuppressive therapies. Lanifibranor has been granted Orphan Drug status for the treatment of SSc by the EMA and the FDA (respectively in November 2014 and March 2015). Orphan Drug status provides certain advantages for the sponsor, such as reduced procedure costs and commercial exclusivity.

About the Phase IIb NATIVE trial

The Phase IIb NATIVE trial is a 24-week randomized double-blind study designed to assess the efficacy of lanifibranor on ballooning and inflammation without worsening of fibrosis. Patients receive either lanifibranor or placebo. This trial also evaluates the safety of lanifibranor treatment. The main inclusion and assessment criteria of the study are based on the hepatic histology of each patient: (i) NASH histological diagnosis according to the NASH Clinical Research Network criteria (steatosis, lobular inflammation of any degree and liver cell ballooning of any amount) and (ii) SAF activity score of 3 or 4 (> 2), SAF Steatosis score ≥ 1 and SAF Fibrosis score < 4 . The primary endpoint of the study is a decrease in relation to the baseline of ≥ 2 points of the SAF activity score combining hepatocellular inflammation and ballooning.

About lanifibranor

Lanifibranor is a next generation panPPAR modulator, designed as a moderately potent and well-balanced PPAR α , γ and δ . This unique profile was conceived in order to obtain an optimal therapeutic margin with strong efficacy and tolerance. Lanifibranor is currently being evaluated in two parallel Phase IIb clinical studies in NASH and SSc as well as in a Phase II trial in diabetic patients with NAFLD (non-alcoholic fatty liver disease).

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 mucopolysaccharidosis 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 Morquio 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.

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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.

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