Inventiva Announces Positive DSMB Review in Phase IIb FASST Trial in Systemic Sclerosis with Lanifibranor

- DSMB recommends trial to continue unchanged
- 145 patients randomized in trial
- Topline results anticipated early 2019

Daix (France) January 4, 2018 – Inventiva, a biopharmaceutical company developing innovative breakthrough therapies, particularly for the treatment of fibrotic diseases, today announced that the Data Safety Monitoring Board (DSMB) has completed its review of the Phase IIb FAAST (For A Systemic Sclerosis Treatment) trial in systemic sclerosis with lanifibranor. After reviewing all safety data, including adverse events, and the study's conduct, the DSMB recommended that the study continue without any modifications to the protocol. Of the 145 randomized patients enrolled into the trial, 100 patients have been treated for 6 months including 54 patients that have already completed the one year treatment. The study is progressing as planned with no specific concerns and topline results are anticipated in early 2019.

About Lanifibranor:

Lanifibranor is a next generation panPPAR modulator designed as a moderately potent and well balanced PPAR α, δ and γ. This unique profile was conceived in order to obtain an optimal therapeutic margin with strong efficacy and tolerance. Lanifibranor displayed an antifibrotic efficacy superior to selective PPARα, PPAR δ or PPARγ agonists in several relevant preclinical models. Inventiva is also conducting a Phase IIb clinical study in NASH with lanifibranor.

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 systemic sclerosis (SSc). Patients will 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 Food and Drug Administration (FDA) and the EMA. Inclusion criteria are based on a MRSS between 10 and 25, and diffuse systemic sclerosis 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 systemic sclerosis by the EMA and the FDA. The orphan drug status provides certain advantages for the sponsor such as reduced procedure costs and commercial exclusivity.

About systemic sclerosis:

Systemic sclerosis is a rare and complex disease affecting the auto-immune system, the microvascular system and conjunctive tissues. This fibrotic disease mainly affects the skin, but also the lungs, the heart, the gastro-intestinal tract, and the kidneys. Due to the progressive failure of different organs, systemic sclerosis is a severe disease

with a high mortality rate. Once patients are diagnosed with systemic sclerosis, generally between the ages of 40 and 50, the median survival period is of 11 years. Close to 170,000 people suffer from systemic sclerosis worldwide, with women outnumbering men by a ratio of more than five to one[1].

The disease owes its original name to scleroderma, the skin condition that it provokes, which derives from the Greek words skleros (hard) and derma (skin). The disease causes severe physical and psycho-social consequences; the former may be fatal for patients whose vital organs are affected. Deeper study of this skin fibrosis has led to its classification into two sub-categories, respectively called limited cutaneous systemic sclerosis and diffuse cutaneous systemic sclerosis. The latter is more serious and is targeted in the FASST trial.

To date, only symptomatic drugs with limited therapeutic effects are available in order to attenuate the consequences of fibrosis progression. However, they do not prevent, delay or reverse the disease's devastating process.

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 with a strong action mechanism permitting the activation of all 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), which is a treatment for three different forms of mucopolysaccharidosis: MPS I or Hurler/Scheie syndromes, MPS II or Hunter syndrome and MPS VI also known as Maroteaux-Lamy 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.

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[1] Journal of Rheumatology, 2013

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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.