

Inventiva's Phase IIb FASST Trial in Systemic Sclerosis with Lanifibranor Completes Enrollment

- ▶ Enrollment complete – 145 patients randomized
- ▶ A total of 47 clinical sites in 10 countries actively recruited patients
- ▶ Headline results expected in early 2019

Daix (France) October 17, 2017 – 06:00 pm CEST – Inventiva, a biopharmaceutical company developing innovative breakthrough therapies, particularly for the treatment of fibrotic diseases, today announced that it has completed the enrollment of its Phase IIb FASST (For A Systemic Sclerosis Treatment) trial in Systemic Sclerosis (SSc) with lanifibranor, formerly known as IVA337. FASST is progressing well and investigators have enrolled and randomized 145 patients. Headline results are expected in early 2019.

“We are pleased to have achieved this important enrollment milestone in the development of lanifibranor for the treatment of systemic sclerosis,” said Dr. Jean-Louis Abitbol, Chief Medical Officer and Head of Development of Inventiva. *“The decision to open new countries and sites has resulted in a larger number of patients recruited and a slightly longer than anticipated recruitment period. We are very grateful to the patients and our network of investigators for the achievement of this important milestone.”*

“The FASST trial protocol meets EMA and FDA approval standards. Therefore, if the results of the FASST Phase IIb are positive, we are very confident that lanifibranor will be successful in the pivotal Phase III,” added Professor Yannick Allanore, Professor of Rheumatology at *Hôpital Cochin* in Paris and co-Principal Investigator of the FASST trial with Professor Chris Denton, Professor of Experimental Rheumatology at University College London.

“Systemic sclerosis is a serious disease with a high unmet medical need. Current treatments mainly manage complications or provide symptomatic relief whereas lanifibranor has the potential to modify the course of the disease, thus representing a significant step forward for patients. We are looking forward to the result of this trial and to lanifibranor further development,” said Dominique Godard, President of the French SSc Association.

Lanifibranor is a next generation panPPAR modulator designed as a moderately potent and well balanced PPAR α , δ and γ agonist. This unique profile was designed in order to obtain an optimal therapeutic margin with strong anti-fibrotic efficacy and tolerance. Preclinical data also demonstrate that lanifibranor has the potential to treat pulmonary arterial hypertension a condition often associated with SSc. Inventiva is also progressing a Phase IIb clinical study in NASH (non-alcoholic steatohepatitis) 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 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 the 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 permitted to continue with 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, with women outnumbering men by a ratio of more than five to one¹.

The disease owes its original name of scleroderma, which derives from the Greek words skleros (hard) and derma (skin), to the skin condition it provokes. 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.