

Inventiva Hits Clinical Milestone with Enrollment of 100th Patient in IVA337 Phase 2b FASST Trial in Systemic Sclerosis (SSc)

- ▶ FASST Phase 2b Clinical Trial on Track to Complete Enrollment in 2nd Half of 2017
- ▶ Topline Results Anticipated in 2nd Half of 2018

Daix (France) April 10, 2017 – 06:00 pm CEST – Inventiva, a biopharmaceutical company developing innovative therapies, particularly to treat fibrosis, announced today that it has achieved an important milestone in its development of IVA337 for the treatment of systemic sclerosis (SSc), by enrolling the 100th patient into the Phase IIb FASST trial. The trial, which began in December 2015, is now 75% enrolled. The Company is currently on track to complete enrollment in the second half of 2017, with topline results expected to be available in the second half of 2018.

“We are pleased that the FASST study is proceeding on schedule, underscoring the interest we are seeing from physicians and patients in IVA337,” said Frédéric Cren, CEO and co-founder of Inventiva. *“To deliver on the recruitment timelines is of major importance for Inventiva. With the opening of additional sites in new countries, we are confident that enrollment will be finalized by the end of this year, delivering the first results in the second half of 2018”* said Pierre Broqua, CSO and co-founder.

“Systemic sclerosis is a fatal orphan disease with no approved treatment. Current treatment is directed mainly toward managing complications and providing symptomatic relief,” said Professor Chris Denton, Professor of Experimental Rheumatology at University College London and co-Principal Investigator of the FASST trial. *“IVA337 has a unique mechanism of action and has demonstrated evidence of a therapeutic benefit in prior studies. It has the potential to be a true disease modifying agent and potentially highly effective treatment in this disease. I look forward to completing this important study and reporting results in 2018.”*

“The anti-fibrotic activity of IVA337 has been demonstrated in preclinical studies, including recent experiments demonstrating anti-fibrotic activities in relevant models of lung and kidney fibrosis,” said Professor Yannick Allanore, Professor of Rheumatology at Hôpital Cochin in Paris and co-Principal Investigator in the FASST trial. *“These studies reinforce the rationale of developing IVA337 in the SSc population. The FASST clinical trial will generate further insight into the beneficial effects of IVA337 in humans, and I look forward to the results next year.”*

FASST is a one-year randomized double-blind study designed to enroll up to a total of 132 patients at 50+ sites across eight European countries. Patients are being administered one of the two doses of IVA337 or placebo. The study protocol, approved by the European Medicines Agency (EMA), has been designed to demonstrate the beneficial effect of IVA337 on progression of SSc. The primary endpoint is a measure of the change in the modified Rodnan skin score, a measure of disease progression accepted by both FDA and the EMA. Inclusion criteria are based on a MRSS (Modified Rodnan Skin Score) 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.

In November 2014, the European Medicines Agency (EMA) granted IVA 337 the orphan drug status for the treatment of systemic sclerosis. The orphan drug status provides certain advantages for the sponsor such as reduced procedure costs and ten years of commercial exclusivity.

“Much in line with this Phase IIb study in which patient enrollment is progressing very well, we are pursuing the execution of our clinical development plan we announced during our initial public offering in February. We remain on schedule to report important clinical results from mid-2018 in our three main indications, which are NASH, MPS VI and systemic sclerosis,” concluded Frédéric Cren, Inventiva’s CEO and co-founder.

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.

IVA337, 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, IVA336, which is a treatment for three different forms of mucopolysaccharidosis: MPS I or Hurler-Scheie syndrome, MPS II or Hunter syndrome and MPS VI also known as Maroteaux-Lamy syndrome. Inventiva has a preclinical stage oncology portfolio.

Inventiva benefits from partnerships with world-leading research entities such as the Institut Curie. Two strategic commercial partnerships, one of which is at clinical stage, have also been developed 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.

¹ Journal of Rheumatology, 2013

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Please refer to the « Document de Base » filed with the Autorité des Marchés Financiers on July 8, 2016 under n° I.16-066, and its update submitted on January 12, 2017 under n° D.16-0535-A01 for additional information in relation to such factors, risks and uncertainties.

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