

Inventiva's lanifibranor found to have good safety profile following first assessment of carcinogenicity studies' results

- ▶ Two-year studies now completed confirming long-term safety of lanifibranor
- ▶ Both studies should be deemed adequate according to preliminary assessment
- ▶ Results to be presented to FDA
- ▶ Results to allow initiation of Phase III clinical trials

Daix (France), August 13, 2018 – Inventiva, a biopharmaceutical company developing innovative therapies in nonalcoholic steatohepatitis (NASH), systemic sclerosis (SSc), and mucopolysaccharidosis (MPS), today reported the successful completion of two two-year carcinogenicity studies with the pan-PPAR agonist lanifibranor.

A preliminary assessment was performed by Dr. Jeri El-Hage, toxicologist and regulatory consultant and expert in the PPAR field at Aclairo Pharmaceutical Development Group, indicating that both studies should be deemed adequate based on correct dosing and good tolerability.

"In my assessment of the results from the studies, it is clear that the toxicological profile of lanifibranor is relatively benign" said Dr. El-Hage. "The studies were well conducted with excellent survival rates and tolerability and results show an improved safety profile compared to other dual- and pan-PPARs. Lanifibranor displays a good cardiac safety profile and in my opinion the results of these studies should allow lanifibranor to enter into Phase III".

The two carcinogenicity studies in rats and in mice were initiated in October 2015 after study protocol approval by the US Food and Drug Administration (FDA). They were conducted by Envigo (United Kingdom), a Contract Research Organization (CRO) with expertise in running similar studies, particularly with compounds from the PPAR class. The studies assessed the effects of three doses of lanifibranor, administered daily for a 104-week period, compared to control groups.

The results of these studies will be presented to the FDA's Executive Carcinogenicity Assessment Committee (ECAC) in order to obtain the authorization to enter into Phase III. The special protocol assessments for the studies had been reviewed by the ECAC and the doses evaluated were approved for both studies.

"With the completion of these carcinogenicity studies, Inventiva has now finalized the regulatory toxicological package necessary to enter into Phase III with lanifibranor," declared Pierre Broqua, Chief Scientific Officer and co-founder of Inventiva. "The data demonstrate a good safety profile and we look forward to receiving feedback from the FDA in the coming months."

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. Inventiva is currently evaluating lanifibranor in two parallel Phase IIb clinical studies in NASH and SSc.

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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