PRESS RELEASE

# Inventiva Announces Positive Results of 12 Month Primate Toxicity Study with IVA337

- No Adverse Clinical Signs Observed at Any Dose-Levels During the Treatment Period

**Daix (France), May 15, 2017 – 6:00pm CEST –** Inventiva, a biopharmaceutical company developing innovative therapies, particularly to treat fibrosis, announced today the results of a 12 month non-human primate toxicology study with its lead drug candidate IVA337, a pan PPAR agonist in phase IIb clinical development in non-alcoholic steato-hepatitis (NASH) and systemic sclerosis (SSc). No adverse clinical signs were observed during the treatment period at any dose-level and none of the typical adverse effects related to the thiazolidinones were observed.

This toxicology study was conducted to meet the regulatory requirements of health authorities including the FDA and EMA. Inventiva is also advancing with two carcinogenity studies of 24 month duration in rodents, and after 18 months of treatment both studies are progressing as planned. Once these are completed, Inventiva will have by mid-2018 the necessary toxicology package required to move into Phase III testing and for regulatory filing.

*"These results will be important for the end of phase IIb discussions with regulatory authorities. Inventiva continues to deliver on its strategy to have IVA337 ready to enter into pivotal trials in NASH and SSc,"* said Dr. Pierre Broqua, Chief Scientific Officer and Cofounder of Inventiva. *"We are impressed by the benign profile of IVA337, which does not show the side effects typically observed with thiazolidinediones or fibrates"* added Dr. Jeri El-Hage, Toxicologist and Regulatory Consultant, expert in the PPAR field at Aclairo Pharmaceutical Development Group.

## Key findings

- No adverse clinical signs were observed during the treatment period at any dose-level tested,
- There were no effects on body weight and heart weight, no haemodilution or creatinine increase,
- Electrocardiography did not reveal any undesirable effects related to IVA337 treatment,
- Ophthalmological examinations did not reveal any undesirable effects related to IVA337 treatment,
- Clinical pathology investigations (hematology, clinical biochemistry and urinalysis) did not reveal any undesirable effects related to IVA337 treatment.

## Study Design

The objective of this study was to evaluate the safety profile of IVA337 following daily oral administration to cynomolgus monkeys over 52 weeks. Forty eight monkeys received a daily oral administration of IVA337 at doses of 100, 250 or 625 mg/kg/day or placebo for 52 weeks. On completion of the treatment period, designated animals were held for a 6-week treatment-free period in order to evaluate the reversibility of any findings.

Inventiva is currently conducting Phase IIb clinical trials with IVA337 in both NASH and SSc, and results are expected in the second half of 2018. In previous clinical studies with IVA337, the drug was well tolerated and safe, in particular there were no changes of creatinine blood levels, liver function tests, CPK, blood pressure, no signal of haemodilution or weight gain.

## 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.

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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.*

*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.*