

## Inventiva Announces Positive DSMB Reviews in both NASH and Systemic Sclerosis Phase IIb Trials with Lanifibranor

- ▶ Both DSMB recommend trials to continue without changing the protocol
- ▶ Lanifibranor safety is confirmed
- ▶ Trials to continue as planned

**Daix (France) June 20, 2018** – Inventiva S.A. (“Inventiva” or the “Company”), a biopharmaceutical company developing innovative therapies in nonalcoholic steatohepatitis (“NASH”), systemic sclerosis (“SSc”) and mucopolysaccharidosis (“MPS”), today announced that the FASST (For A Systemic Sclerosis Treatment) Data Safety Monitoring Board (“DSMB”) held its third and last meeting before the end of the trial of lanifibranor in SSc. Similarly to the conclusions of the first two DSMBs, the board recommended that the study continue without any modification to the protocol. Similarly the NATIVE (NASH Trial to Validate IVA337 Efficacy) DSMB met for the first time and after reviewing all safety data came to a similar conclusion and recommended to continue the study without any modification of the protocol. The positive outcomes of these two DSMBs confirm the good safety of lanifibranor, already demonstrated in long-term toxicological studies as well as in phase I and phase II clinical trials. Both studies are progressing as planned with no specific concerns and topline results are anticipated in early 2019 for the FASST trial in SSc and second half of 2019 for the NATIVE trial in NASH.

### About Lanifibranor:

Lanifibranor is a next generation panPPAR modulator designed as a moderately potent and well balanced PPAR  $\alpha$ ,  $\delta$  and  $\gamma$ . 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 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 the Phase IIb NATIVE trial:

The Phase IIb NATIVE trial is a 24-week randomized double-blind study designed to assess the efficacy of lanifibranor on ballooning and inflammation without worsening of fibrosis. Patients will receive either lanifibranor or placebo. This trial will also evaluate the safety of lanifibranor treatment. The main inclusion and assessment criteria of the study are based on the hepatic histology of each patient: (i) NASH histological diagnosis according to the NASH Clinical Research Network criteria (steatosis, lobular inflammation of any degree and liver cell ballooning of any amount) and (ii) SAF activity score of 3 or 4 ( $> 2$ ), SAF Steatosis score  $\geq 1$  and SAF Fibrosis score  $< 4$ . The primary endpoint of the study is a decrease in relation to the baseline of  $\geq 2$  points of the SAF activity score combining hepatocellular inflammatory and ballooning.

**About Inventiva:** [www.inventivapharma.com](http://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.

## Contacts

### **Inventiva**

Frédéric Cren  
Chief Executive Officer  
[info@inventivapharma.com](mailto:info@inventivapharma.com)  
+ 33 3 80 44 75 00

### **Brunswick**

Julien Trosdorf / Yannick Tetzlaff  
Media relations  
[inventiva@brunswickgroup.com](mailto:inventiva@brunswickgroup.com)  
+ 33 1 53 96 83 83

### **LifeSci Advisors**

Chris Maggos  
Investor relations  
[chris@lifesciadvisors.com](mailto:chris@lifesciadvisors.com)  
+41 79 367 6254

## Important Notice

*This press release contains forward-looking statements, forecasts and estimates with respect to the clinical development plans, business and regulatory strategy, and anticipated future performance of Inventiva and of the market in which it operates. Certain of these statements, forecasts and estimates can be recognized by the use of words such as, without limitation, "believes", "anticipates", "expects", "intends", "plans", "seeks", "estimates", "may", "will" and "continue" and*

*similar expressions. Such statements are not historical facts but rather are statements of future expectations and other forward-looking statements that are based on management's beliefs. These statements reflect such views and assumptions prevailing as of the date of the statements and involve known and unknown risks and uncertainties that could cause future results, performance or future events to differ materially from those expressed or implied in such statements. Actual events are difficult to predict and may depend upon factors that are beyond Inventiva's control. There can be no guarantees with respect to pipeline product candidates that the candidates will receive the necessary regulatory approvals or that they will prove to be commercially successful. Therefore, actual results may turn out to be materially different from the anticipated future results, performance or achievements expressed or implied by such statements, forecasts and estimates. Given these uncertainties, no representations are made as to the accuracy or fairness of such forward-looking statements, forecasts and estimates. Furthermore, forward-looking statements, forecasts and estimates only speak as of the date of this press release. Readers are cautioned not to place undue reliance on any of these forward-looking statements.*

*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.*

*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.*