

# H1 2019<sup>1</sup> Financial Information and Corporate Business Update

- Cash and cash equivalents of €37.1m as at June 30, 2019, in line with expectations
- ► H1 revenues at €1.2m
- Significant progress in NASH program, notably in the recruitment of patients in the NATIVE Phase IIb clinical study
- Completion of patient recruitment in the iMProveS Phase IIa clinical study evaluating odiparcil for the treatment of mucopolysaccharidosis type VI (MPS VI)
- New data confirming the potential of the YAP-TEAD oncology program
- ► Launch of new clinical study for the treatment of psoriasis with ABBV-157, the drug candidate resulting from the partnership with AbbVie

**Daix (France), July 30, 2019** – Inventiva (Euronext: IVA), a clinical-stage biopharmaceutical company developing oral small molecule therapies for the treatment of diseases in the areas of fibrosis, lysosomal storage disorders and oncology, today reported its cash position as at June 30, 2019 and revenues for the first half of 2019, and provided a corporate business update.

# **Key financial results**

As at June 30, 2019, Inventiva's **cash and cash equivalents** were €37.1 million, vs. €56.7 million on December 31, 2018, in line with Company expectations. Net cash flow related to operating activities amounted to -€19.6 million in the first half of 2019 (vs. -€15.3 million in the first half of 2018). R&D expenses for the semester, mainly driven by lanifibranor and odiparcil programs, were up 21.8% compared to the first half of 2018.

Revenues for the first half of 2019 amounted to €1.2 million, compared to €1.4 million in the first half of 2018.

#### Key highlights of the second quarter

# Lanifibranor for the treatment of non-alcoholic steatohepatitis ("NASH")

In May, the U.S. Food and Drug Administration (FDA) lifted for lanifibranor the clinical hold in place on the peroxisome proliferator-activated receptor (PPAR) target class. This decision enables Inventiva to conduct clinical trials equal to or longer than six months evaluating lanifibranor for the treatment of NASH. It followed the review of the two-year carcinogenicity studies by the FDA's Executive Carcinogenicity Assessment Committee (ECAC). This decision confirms lanifibranor's benign safety profile and represents a key milestone for Inventiva as it removes a key obstacle that had prevented the Company from initiating long-term Phase III clinical trials necessary to obtain marketing approval with lanifibranor for the treatment of NASH.

<sup>&</sup>lt;sup>1</sup> Financial information not audited in accordance with IFRS standards.



The NATIVE (NASH Trial To Validate IVA337 Efficacy) Phase IIb clinical study is progressing as planned and, at the end of June, 211 patients out of a target of 225 had been randomized in the study. The results will be published, as expected, in the first half of 2020.

#### Odiparcil for the treatment of mucopolysaccharidoses ("MPS")

Early June, Inventiva announced the completion of patient recruitment in its iMProveS (improve MPS treatment) Phase IIa clinical study in Europe evaluating odiparcil for the treatment of mucopolysaccharidosis type VI (MPS VI).

The patients participating in the trial are distributed among the various arms, with fifteen patients being treated with enzyme replacement therapy (ERT) and receiving one of the two doses of odiparcil or placebo and five patients not being treated with ERT and only receiving the high dose of odiparcil. The headline results of the fifteen ERT-treated patients are expected by the end of the year. The results of the five patients not being treated with ERT are expected during the first quarter of 2020.

#### YAP-TEAD in the field of oncology

In May, Inventiva presented new results from its YAP-TEAD oncology program at the AACR Special Conference on The Hippo Pathway: Signaling, Cancer, and Beyond. These results showed that Inventiva's YAP-TEAD inhibitors significantly reduced tumor growth in Malignant Pleural Mesothelioma (MPM) xenograft and orthotopic models. In addition, synergistic effects were seen in a three-dimensional spheroid model suggesting that Inventiva's YAP-TEAD inhibitors, when used in combination with existing chemotherapeutics, could attenuate multidrug resistance and re-sensitize chemo-resistant cancer cells.

Following these promising results, Inventiva has decided to expand its research to other cancer indications as well as other combination strategies where standard of care agents are proven to be ineffective and where YAP is activated.

# ABBV-157 for the treatment of moderate to severe psoriasis

AbbVie has initiated a new clinical study with ABBV-157, the drug candidate resulting from its collaboration with Inventiva, aiming at assessing the compound's pharmacokinetics, safety and tolerance in healthy volunteers and in patients with chronic plaque psoriasis. Inventiva could receive milestone payments as well as royalties on future sales. For further information on the new clinical trial, please visit: <a href="https://clinicaltrials.gov/ct2/show/NCT03922607">https://clinicaltrials.gov/ct2/show/NCT03922607</a>

#### **Creation of a Scientific Advisory Board**

Inventiva recently announced the creation of its Scientific Advisory Board (SAB) to provide scientific review and advice to the Company's management with regards to its R&D activities and product portfolio. The SAB covers Inventiva's key areas of research and development with a particular focus on NASH, MPS and oncology. The SAB also supports Inventiva's management regarding the preclinical and clinical aspects of the Company's development programs and its global scientific policy, including targets, fields of research, partnerships and market access.

# Approval and implementation of a redundancy plan following the termination of the systemic sclerosis ("SSc") program

Following the termination of the SSc program in February 2019 due to the failure to meet the primary endpoint of the FASST Phase IIb clinical study, the Company implemented a redundancy plan in the second quarter which was subject to a corporate agreement signed on June 11, 2019; combined with the non-renewal of fixed-term



contracts, the Company's total workforce will be reduced from 118 to approximately 90 employees by the end of the year.

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# **Key milestones expected**

- Completion of patient recruitment in the NATIVE Phase IIb clinical study evaluating lanifibranor for the treatment of NASH
- Completion of patient recruitment in the Phase II clinical study evaluating lanifibranor for the treatment of NAFLD in patients with type 2 diabetes
- Launch of a new biomarker study in patients with MPS VI
- Results of the iMProveS Phase IIa clinical study
- Selection of the clinical candidate for the YAP-TEAD oncology program

#### **Upcoming investor conferences**

- Portzamparc Biotech Conference, Paris, September 10, 2019
- SFAF Meeting, Paris, September 17, 2019
- Forum Lyon Pôle Bourse, Lyon, September 25, 2019
- KBC Biotech Conference, Brussels, September 27, 2019
- Large & MidCap Event, Paris, October 14-15, 2019
- HC Wainwright NASH Conference, New York, October 21, 2019
- Gilbert Dupont NASH Day, Paris, October 29, 2019
- KOL and investors' meeting at the American Association for the Study of Liver Diseases (AASLD) conference, Boston, November 9, 2019
- Jefferies 2019 London Healthcare Conference, London, November 20-21, 2019

# **Next financial results publication**

H1 2019 financial results: Thursday, September 26, 2019 (after market close)

#### **About Inventiva**

Inventiva is a clinical-stage biopharmaceutical company focused on the development of oral small molecule therapies for the treatment of diseases with significant unmet medical needs in the areas of fibrosis, lysosomal storage disorders and oncology.

Leveraging its expertise and experience in the domain of compounds targeting nuclear receptors, transcription factors and epigenetic modulation, Inventiva is currently advancing two clinical candidates — lanifibranor and odiparcil — in non-alcoholic steatohepatitis ("NASH") and mucopolysaccharidosis ("MPS"), respectively, as well as a deep pipeline of earlier stage programs.

Lanifibranor, its lead product candidate, is being developed for the treatment of patients with NASH, a common and progressive chronic liver disease. Inventiva is currently evaluating lanifibranor in a Phase IIb clinical trial for the treatment of this disease for which there are currently no approved therapies.



Inventiva is also developing odiparcil, a second clinical-stage asset, for the treatment of patients with MPS, a group of rare genetic disorders. The Company is currently investigating odiparcil in a Phase IIa clinical trial for the treatment of patients with the MPS VI subtype.

In parallel, Inventiva is in the process of selecting an oncology development candidate for its Hippo signalling pathway program. The Company has established two strategic partnerships with AbbVie and Boehringer Ingelheim in the areas of autoimmune diseases and idiopathic pulmonary fibrosis ("IPF") respectively. AbbVie has started the clinical development phase of ABBV-157, a drug candidate for the treatment of moderate to severe psoriasis resulting from its collaboration with Inventiva. Both collaborations entitle Inventiva to receive milestone payments upon the achievement of pre-clinical, clinical, regulatory and commercial milestones, in addition to royalties on any approved products resulting from the partnerships.

The Company has a scientific team of approximately 70 people with deep expertise in the fields of biology, medicinal and computational chemistry, pharmacokinetics and pharmacology a well as in clinical development. It also owns an extensive library of approximately 240,000 pharmacologically relevant molecules, around 60% of which are proprietary, as well as a wholly-owned research and development facility.

Inventiva is a public company listed on compartment C of the regulated market of Euronext Paris (Euronext: IVA – ISIN: FR0013233012). <a href="https://www.inventivapharma.com">www.inventivapharma.com</a>

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#### **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 12, 2019 under n° R.19-006 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.