

## Q1 2019 Financial Information and Corporate Business Update<sup>1</sup>

- Cash and cash equivalents of €47.3m as at 31 March 2019, in line with expectations
- Revenues increase to €1.0m in Q1 2019 compared to Q1 2018
- Significant progress in NASH, mucopolysaccharidosis type VI (MPS VI) and oncology programs
- New clinical study planned for the treatment of psoriasis with ABBV-157, the drug candidate resulting from the partnership with AbbVie

Daix (France), May 15, 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 and revenues for the first quarter 2019, and provided a corporate business update.

### **Key financial results**

As at 31 March 2019, Inventiva's **cash and cash equivalents** were €47.3 million, vs. €56.7 million on 31 December 2018, in line with the Company's expectations. Inventiva's cash burn was primarily driven by its ongoing preclinical and clinical studies.

Net cash flow amounted to -€9.4 million in the first quarter of 2019, including -€8.6 million from operating activities (vs. -€7.7 million in the first quarter of 2018). R&D expenses for the quarter, mainly driven by lanifibranor and odiparcil programs, were up 34.4% compared to the first quarter of 2018.

The Company's **revenues** for the first quarter of 2019 increased to €1.0 million from €0.5 million in the first quarter of 2018.

### **Key highlights**

### Lanifibranor in the treatment of systemic sclerosis ("SSc")

The development of lanifibranor for the treatment of systemic sclerosis was discontinued following the publication in February 2019 of the results of the FASST Phase IIb clinical study, which did not meet its primary endpoint. However, the same study demonstrated that lanifibranor was, in a fragile and poly-medicated population, associated with a favorable safety profile. These good tolerability data reinforce the rationale for developing lanifibranor in NASH. Given the SSc results, the Company is now focusing its resources and its teams on its three priority programs (lanifibranor in NASH, odiparcil in MPS VI and YAP-TEAD in oncology), and on its partnership with Boehringer Ingelheim for the treatment of idiopathic pulmonary fibrosis.

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



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

In its NATIVE Phase IIb clinical study evaluating lanifibranor in the treatment of NASH, Inventiva randomized its first patient in the US in February 2019. At the end of April 2019, 178 patients out of the 225 patients expected to be enrolled in the study had been randomized, and 96 patients had already completed the six-month study. The NATIVE study is therefore progressing as plannned, and results are expected in the first half of 2020.

The study's DSMB (Data Safety Monitoring Board) met for the third time in March 2019. After analyzing all the safety data from the study, it recommended — as it did in both previous DSMB meetings — the continuation of the study without changing the protocol, thereby confirming once again lanifibranor's good safety profile.

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

The iMProveS Phase IIa clinical study evaluating odiparcil in the treatment of MPS VI successfully completed its first phase with the first meeting of the DSMB in October 2018. After analysis of the drug candidate's safety data in MPS VI patients, the DSMB recommended the continuation of the study. Since then, the DSMB met a second time in March 2019 and again recommended the study's continuation without any modification to the protocol. The study results are expected in the second half of 2019 as planned.

In early March 2019, the U.S. Food and Drug Administration (FDA) granted Rare Pediatric Disease Designation (RPDD) status to odiparcil. This status confirms odiparcil's eligibility to obtain a Priority Review Voucher, to be used for another New Drug Application (NDA) or for a Biologics License Application (BLA). These vouchers can reduce the FDA's review time from 12 to six months. They can be used by the Company or sold or transferred to a third party. Inventiva will receive this voucher once the FDA has granted marketing authorisation to odiparcil.

### YAP-TEAD in the field of oncology

The selection of the drug candidate for the YAP-TEAD program in oncology is ongoing and the initiation of its preclinical development is expected to begin this year.

Furthermore, the Company presented new results in the treatment of malignant pleural mesothelioma during the AACR (American Association for Cancer Research) special conference dedicated to the Hippo pathway, held early this month in San Diego, USA. These results showed the potential of Inventiva's molecules to significantly reduce tumor growth, mitigate drug resistance and restore the sensitivity of chemoresistant cancer cells. Following these promising results, Inventiva 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 activation is involved.

# ABBV-157, the drug candidate resulting from the partnership with AbbVie, for the treatment of moderate to severe psoriasis

AbbVie continues the clinical development of ABBV-157, the drug candidate resulting from its collaboration with Inventiva. Following a first Phase I clinical trial, AbbVie recently reported its intention to initiate a new clinical study with ABBV-157, aiming at assessing the compound's pharmacokinetics, safety and tolerance in healthy volunteers and in patients with chronic plaque psoriasis. This confirms the drug candidate's potential as well as AbbVie's determination to develop and commercialize this compound, for which 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>



•••

### **Key milestones expected**

- End of recruitment in the NATIVE Phase IIb clinical study evaluating lanifibranor for the treatment of NASH
- End of recruitment in the Phase II clinical study evaluating lanifibranor for the treatment of NAFLD in patients with type 2 diabetes
- End of recruitment in the iMProveS Phase IIa clinical study evaluating odiparcil for the treatment of MPS VI
- Launch of a new biomarker study in patients with MPS VI
- Results of the iMProveS Phase IIa clinical study
- Selection of the preclinical candidate for the YAP-TEAD oncology program
- Launch of a new clinical study with ABBV-157 in healthy volunteers and in patients with chronic plaque psoriasis.

### **Upcoming investor conferences**

- Jefferies Healthcare Conference, New York, 4-7 June 2019
- European MidCap Event, Paris, 18-19 June 2019
- HealthTech Investor Day, Paris, 24-25 June 2019

### **Upcoming meetings**

- Annual General Meeting: Monday, 27 May 2019, 2:00 pm (CEST) in Dijon, France
- \$1 2019 revenues and cash position: Tuesday, 30 July 2019 (after market close)

### About d'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 adult patients with the MPS VI subtype.

In parallel, Inventiva is in the process of selecting an oncology development candidate for its Hippo signaling pathway program and is advancing pre clinical programs for the treatment of autoimmune diseases and idiopathic



pulmonary fibrosis ("IPF") in collaboration with AbbVie and Boehringer Ingelheim respectively. AbbVie is investigating ABBV 157, a clinical development candidate resulting from its collaboration with Inventiva, in a Phase I clinical trial for the treatment of moderate to severe psoriasis. 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 90 people with deep expertise in the fields of biology, medicinal and computational chemistry, pharmacokinetics and pharmacology. It also owns an extensive library of approximately 240,000 pharmacologically relevant molecules, 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). www.inventivapharma.com

#### **Contacts**

Inventiva
Frédéric Cren
Chairman & CEO
info@inventivapharma.com
+33 3 80 44 75 00

Brunswick Group
Yannick Tetzlaff /
Tristan Roquet Montegon
Media relations
inventiva@brunswickgroup.com
+33 1 53 96 83 83

LifeSci Advisors
Monique Kosse
Investor relations
monique@lifesciadvisors.com
+1 212 915 3820

### **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.

•