Inventiva: First-half 2017 results

- On track to complete enrolment in systemic sclerosis (SSc) trial (FASST) for lanifibranor by Q4 2017
- Opening of new clinical sites to improve recruitment rate for clinical trial (NATIVE) of lanifibranor in NASH
- First patient recruitment for odiparcil phase IIa clinical trial (iMProveS) in MPS VI planned by Q4 2017
- Financial position strengthened

Daix (France), September 26, 2017 – 6:30pm CEST - Inventiva, a biopharmaceutical company developing innovative therapies, particularly to treat fibrosis, provided a business update and reported its interim financial results for the six months to June 30, 2017.

Business highlights

Lanifibranor (formerly IVA337)

- Lanifibranor granted as the international non-proprietary name (INN) for IVA337, the first next generation panPPAR α, δ and γ to receive the fibranor suffix
- Positive results from the 12-month toxicity study of lanifibranor on primates: no adverse clinical signs were observed and none of the typical adverse effects related to PPARγ were observed
- Phase IIb NATIVE trial in NASH ongoing in Europe, Australia and Canada
- Data presented at 2017 International Liver Congress, the European Association for the Study of the Liver's (EASL) annual conference, support the potential of lanifibranor as a treatment for NASH
- Enrollment on target in Phase IIb FASST study in patients with systemic sclerosis (SSc)
- Presentation of the latest results on lanifibranor at the 15th International Workshop on Scleroderma Research in the United States demonstrating its therapeutic potential in treating the vascular complications associated with SSc

Odiparcil (formerly IVA336)

- Phase IIa iMProveS study for patients with MPS VI, to begin enrollment before year end 2017
- Launch of the biomarkers study for odiparcil in the United States
- Award of orphan drug designation for odiparcil as a treatment for MPS VI in the United States and Europe
- New preclinical data on odiparcil presented at the MPS Society's National Conference showing its efficacy in several organs where enzyme replacement therapies are not efficacious
- Strengthening of odiparcil intellectual property rights in the United States

Partnerships with AbbVie and Boehringer Ingelheim

- Extension of the collaboration with AbbVie to discover new oral ROR-γ antagonists drug candidates. ABBV-553 project stopped
- Exercise of the option by Boehringer Ingelheim to jointly develop potential new treatments to treat idiopathic pulmonary fibrosis (IPF) triggering a €2.5 million milestone payment (received September, 22)

Financial highlights

H1 2017

- Successful IPO on Euronext Paris
- Significant increase in the cash position to €64.4 million at June 30, 2017

Key newsflow and expected milestones

H2 2017

- Complete the enrollment of the Phase IIb FASST study of lanifibranor in SSc
- Opening of new clinical sites for the Phase IIb NATIVE clinical trial of lanifibranor in NASH
- Results of biomarker study for odiparcil
- Begin enrolment for the Phase IIa iMProveS study of odiparcil in patients with MPS VI

2018

- Results of Phase IIb FASST study of lanifibranor in SSc
- Results of the 2-year carcinogenicity study with lanifibranor
- Complete enrollment of the Phase IIb NATIVE study in NASH
- Results of the Phase IIa iMProveS study of odiparcil in MPS VI

Key first-half 2017 financial figures

Key figures (in thousands of euros)	**at June 30**	
IFRS – Unaudited data	**First-half 2017**	**First-half 2016**
Profit on ordinary activities	**2,658**	**4,140**
Other recurring operating income	2,596	2,596
Research costs	(13,242)	(10,881)
Marketing – business development	(238)	(260)
General and administrative expenses	(2,668)	(1,763)
Recurring operating profit (loss)	**(10,893)**	**(6,168)**
Other non-recurring operating income	255	-
Other non-recurring operating expenses	(704)	(449)
Operating profit (loss)	**(11,343)**	**(6,617)**
Financial income	243	277
Financial expense	(19)	(21)
Net financial items	**224**	**256**
Income tax	1,337	2,276
Net income (loss)	**(9,781)**	**(4,085)**

First-half 2017 profit on ordinary activities of €2.7 million included higher service revenues. The €2.5 million milestone payment by Boehringer Ingelheim when it exercised its option under the collaboration agreement with Inventiva in not yet included. In the first half of 2016, Inventiva's profit on ordinary activities came to €4.1 million, including non-recurring income linked to the receipt of AbbVie's second milestone payment.

First-half 2017 R&D expenditure came to €13.2 million, up 22% compared with the first half of 2016. This was chiefly attributable to the increased costs incurred in Phase 2b clinical trials as a treatment for NASH and systemic sclerosis with lanifibranor (formerly IVA337) and in the clinical trial currently being prepared of odiparcil (formerly IVA336) as a treatment for MPS VI. General and administrative expenses totaled €2.7 million, and these now reflect the recurring costs associated with the Company's listed status.

All in all, Inventiva's operating loss came to €11.3 million (compared with a loss of €6.6 million in the first half of 2016) and its net loss to €9.8 million (compared with a €4.1 million loss in the first half of 2016).

During the period, Inventiva used €5.5 million in cash, without taking into account the €45 million in net proceeds it raised from its IPO on Euronext's regulated market in Paris on February 15, 2017. It received the latest €6.2 million payment from Abbott in the first half of the year, and thus the trend was the same as in operating income before non-recurring items reflecting the ongoing R&D drive.

At June 30, 2017, it held €64.4 million in cash and cash equivalents, compared with €24.8 million at December 31, 2016. Its cash position was strengthened significantly by the IPO. It's important to note that this figure does not reflect the impact of the €2.5 million milestone payment by Boehringer Ingelheim when it exercised its option under the collaboration agreement with Inventiva or the receipt of the €3.6 million research tax credit on August 10, 2017.

Interim financial results were approved by the Board of Directors on September 25, 2017. Auditors issued a limited examination report. For more details, Inventiva's Interim Financial Report is now available for download from the Company's web site: www.inventivapharma.com

Business highlights

Lanifibranor secured as the international non-proprietary name (INN) for IVA337, the first next generation panPPAR α, δ and γ to receive the fibranor suffix

The World Health Organization (WHO) granted the international non-proprietary name (INN) of lanifibranor to IVA337, Inventiva's flagship drug candidate, currently in phase IIb development trials as a treatment for systemic sclerosis (SSc) and in non-alcoholic hepatic steatosis (NASH). Lanifibranor is the first next-generation panPPAR α, δ and γ to receive the fibranor suffix.

Positive results from the 12-month toxicity study of lanifibranor on primates: no adverse clinical signs were observed and none of the typical adverse effects related to PPARγ were observed

In May, the company announced results of a 12 month non-human primate toxicology study with lanifibranor. No adverse clinical signs were observed during the treatment period at any dose-level and none of the typical adverse effects related to PPARγ were observed. The company is also progressing two 24 month carcinogenicity studies in rodents and, once these are completed, it will have by mid-2018 the necessary toxicology package required to potentially move into Phase III clinical trials and subsequent regulatory filing.

Lanifibranor as a treatment for NASH

Phase IIb NATIVE trial as a treatment for NASH ongoing in Europe, Australia and Canada

Initiated in February 2017, NATIVE (NASH Trial to Validate IVA337 Efficacy) is a randomized, double-blind, placebo-controlled, multi-center, Phase IIb clinical trial in NASH patients. The study will investigate the safety and efficacy of two doses of lanifibranor (800 and 1200 mg/day) over a 24-week period. Enrollment in the Phase IIb NATIVE study is progressing, but due to increased competition for patients at clinical trial sites, is running behind the original schedule. Inventiva plans to open new sites in countries where the study is currently being performed (Europe, Australia and Canada). Results from this study are now anticipated early 2019, versus the previous expectation of mid-2018.

Data presented at 2017 International Liver Congress, the European Association for the Study of the Liver's (EASL) annual conference, support the potential of lanifibranor as a treatment for NASH

Pre-clinical work on lanifibranor was featured in a poster presentation at the 2017 International Liver Congress™ which took place in Amsterdam, in April. The findings demonstrated that lanifibranor inhibits the development of NASH through the normalization of different metabolic parameters such as insulin-resistance, activation of fatty acid β-oxidation, and inhibition of the inflammasome known to be a trigger of liver inflammation and fibrosis. In addition lanifibranor produces a strong reversion of established liver fibrosis, due especially to its PPARγ activity.

Pre-clinical data supporting the therapeutic potential of lanifibranor for the treatment of NASH were published in the June 19th edition of Hepatology Communications. Presentations on Inventiva's NASH program were scheduled for the NASH Symposium in Paris in July and during the NASH Summit Europe in Frankfurt in October.

Lanifibranor as a treatment for systemic sclerosis (SSc)

Enrollment on target in Phase IIb FASST study in patients with systemic sclerosis

The Phase IIb FASST (For A Systemic Sclerosis Treatment) study of lanifibranor as a treatment for systemic sclerosis (SSc) now has over 125 randomized patients, just shy of its target of at least 132 patients. Enrollment should thus be completed as planned by the end of the year. The preliminary study results are expected, on schedule, in the second half of 2018. The 48-week FASST study is measuring changes from baseline in the Modified Rodnan Skin Score for two different doses of lanifibranor, compared to placebo.

Presentation of the latest results on lanifibranor at the 15th International Workshop on Scleroderma Research in the United States demonstrating its therapeutic potential in treating the vascular complications associated with SSc

In August, Inventiva presented the latest results with lanifibranor at the 15th International Workshop on Scleroderma Research at the University of Pittsburgh in the United States. The abstract entitled "PAN-PPAR Agonist IVA337 is Effective in the Prevention of Experimental Lung Fibrosis and Pulmonary Hypertension" was selected as one of the best articles presented at the workshop.

The new data generated show that lanifibranor induces a marked protection from the development of lung fibrosis with restoration of respiratory capacity and inhibits pulmonary arteries remodeling with positive impact on pulmonary artery pressure. This large spectrum of activity demonstrates in addition to the previously positive effects demonstrated on skin fibrosis, the therapeutic potential of lanifibranor on cardiorespiratory involvements in SSc patients.

Odiparcil (formerly IVA336)

Phase IIa iMProveS study for patients with MPS VI, to begin enrollment before year end 2017

The iMProveS clinical study will be a 26-week study designed to demonstrate the safety, tolerability, and efficacy of odiparcil in 24 adult MPS VI patients and will be conducted at two European clinical sites. If the results of this study are positive, the company plans to pursue a pivotal Phase III study of odiparcil in patients with MPS VI.

Launch of the biomarkers study for odiparcil in the United States

In support of the odiparcil clinical program, the company is currently running a non-interventional study at the Children's Hospital and Research Center of Oakland (US) under the supervision of Prof. Paul Harmatz. The aim of the study is to determine whether assessment of GAG (glycosaminoglycans) storage in white blood cells is a potential efficacy biomarker. The study is expected to be completed in September, with results announced by the end of this year.

Award of orphan drug designation for odiparcil as a treatment for MPS VI in the United States and Europe

In August 2017, the US Food and Drug Administration (FDA) and the European Medicines Agency (EMA) both granted odiparcil (formerly known as IVA336) orphan drug designation as a treatment for MPS VI. These designations confirm odiparcil's potential to improve the existing therapeutic options.

Orphan Drug Designation is granted by the FDA to novel therapeutics for diseases or conditions affecting fewer than 200,000 patients in the U.S. or greater than 200,000 patients if there is no reasonable expectation that the production cost of the drug will be covered by its sales. The designation allows the drug developer to be eligible for a seven-year period of U.S. marketing exclusivity upon approval of the drug, as well as, in some cases, tax credits for clinical research costs, the ability to apply for annual grant funding, clinical trial design assistance, and the waiver of Prescription Drug User Fee Act (PDUFA) filing fees.

The European Medicines Agency (EMA) grants Orphan Drug Designation to support the development of medicines for the treatment, prevention or diagnosis of a disease that is life-threatening or chronically debilitating and that affect no more than 5 in 10,000 individuals in the European Union. Orphan drug designation allows for companies to receive development incentives, such as protocol assistance, reduced fees for regulatory activities, and up to ten years of market exclusivity in the EU upon marketing approval for the designated indication.

New preclinical data on odiparcil presented at the MPS Society's National Conference showing its efficacy in several organs where enzyme replacement therapies are not efficacious

In July Professor Chris Hendriksz (FYMCA Medical Ltd. and University of Pretoria, South Africa) presented in a closed session at the MPS Society National Conference new preclinical data on odiparcil which further supports its potential to be the first orally available substrate reduction therapy for MPS VI patients. The data, generated in a genetic mouse model for MPS VI, demonstrated that odiparcil restored a normal corneal structure in the eye, reduced GAG accumulation in the liver, kidney, spleen, heart, eye, and skin of diseased animals and also produced a dose-dependent reduction of cartilage thickness in the trachea and femoral growth plate. Mobility was also improved by odiparcil in the diseased animals.

Strengthening of odiparcil intellectual property rights in the United States

In February 2017, a patent protecting the use in the United States of odiparcil for the treatment of MPS VI was granted. With the patent granted in 30 European countries, Inventiva's exclusive use of odiparcil in all of its key markets is now secured until October 2034. In addition, Inventiva has submitted divisional patent applications in Europe and the United States in order to protect the use of odiparcil for the treatment of other forms of mucopolysaccharidoses (MPS). These patent applications have been approved in Europe and are currently under review in the US.

Partnerships with AbbVie and Boehringer Ingelheim

Extension of the collaboration with AbbVie to discover new oral drug candidates that are ROR-γ antagonists. ABBV-553 program stopped

In September 2017, Inventiva and AbbVie announced that Abbv-553, a potent orally active selective antagonist of ROR-γ, which previously underwent a Phase I clinical trial as a treatment for moderate to severe psoriasis and had given rise to several milestone payments to Inventiva, had been stopped. A new collaboration program to discover and develop new oral ROR-γ antagonists has consequently been initiated. Under this program, Inventiva will receive undisclosed fees for research services and milestone payments when a new drug candidate is identified. Inventiva will also be eligible for development and sales milestones as well as royalties on sales.

Exercise of the option by Boehringer Ingelheim to jointly develop potential new treatments to treat idiopathic pulmonary fibrosis (IPF) triggering a €2.5 million milestone payment (received September, 22)

In September 2017 Boehringer Ingelheim exercised its option under the May 2016 collaboration agreement with Inventiva for the research and discovery of new drugs.

The joint research team has validated a new fibrosis target and data generated in the program supports its therapeutic potential in fibrotic conditions and Idiopathic pulmonary fibrosis (IPF) has been selected as the first indication to be targeted. Boehringer Ingelheim's execution of this option triggers a milestone payment to Inventiva of €2.5 million.

To recap, under this collaboration agreement Inventiva is eligible to receive research funding, milestone payments of up to €170 million and tiered royalty payments for any commercial products resulting from this collaboration.

Next financial press release:

- **Third-quarter 2017 revenues**: November 7, 2017 (after market close)

Next investor conferences:

- Healthcare and Biotechnology Field Trip, Paris, September 26
- KBC Biotech and Healthcare Conference, New York, September 28
- European Large & Midcap Event, Paris, October 4-5
- Jefferies 2017 London Healthcare Conference, London, November 15-16
- 29TH Annual Piper Jaffray Healthcare Conference, New York, November 28-29
- Salon Actionaria, Paris, November 23-24
- Geneva European Midcap Event, Geneva, November 28-29

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 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, odiparcil, which is a treatment for three different forms of mucopolysaccharidosis: MPS I or Hurler/Scheie syndromes, 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 have also been established 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 référence » filed with the Autorité des Marchés Financiers on April 26, 2017 under n° R.17-025 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.