Inventiva Announces First-half 2017 Financial and Corporate Update

Daix (France) July 05, 2017 – 7:15pm CEST – Inventiva, a biopharmaceutical company developing innovative therapies, particularly to treat fibrosis, today published its first-half 2017 revenues and cash position and provided a corporate update.

H1 2017 Revenues and Cash position[1]

Inventiva's revenues[1] for the first half of 2017 totaled €2.7 million including an increase in sales in services. This compares to revenues of €4.1 million in H1 2016, when Inventiva received a second milestone from AbbVie whereas no non recurrent revenues were received in H1 2017.

As of June 30, 2017, Inventiva's cash and cash equivalents[1] stood at €64 million, up from €24.8 million as of December 31, 2016. Inventiva's cash position was greatly reinforced by the €48.5 million raised during the IPO on the regulated market of Euronext Paris on February 15, 2017.

Development Programs

Phase IIb trial investigating IVA337 in NASH ongoing

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 IVA337 (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. To accelerate trial enrollment and reduce the deviation from the original schedule, the company plans to open additional trial sites in new countries. Results from this study are now anticipated early 2019, versus the previous expectation of mid-2018.

In May, the company announced results of a 12 month non-human primate toxicology study with IVA337. 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. 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.

Data presented at 2017 International Liver Congress support the potential of IVA337 as a treatment for NASH

Pre-clinical work on IVA337 was featured in a poster presentation at the 2017 International Liver Congress™ which took place in Amsterdam, in April. The findings demonstrated that IVA337 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.

Pre-clinical data supporting the therapeutic potential of IVA337 for the treatment of NASH were published in the June 19th edition of Hepatology Communications.

[1] unaudited

Presentations on Inventiva's NASH program are planned for the NASH Symposium in Paris in July and during the NASH Summit Europe in Frankfurt in October.

Enrollment on target in Phase IIb FASST study of IVA337 in patients with systemic sclerosis

The Phase IIb FASST (For A Systemic Sclerosis Treatment) study of IVA337 in patients with SSc has now 116 patients randomized out of a 132 target and remains on track for completion by the end of this year with results expected, as planned, in the second half of 2018. This 48-week study is measuring changes from baseline in the Modified Rodnan Skin Score for two different doses of IVA337, compared to placebo.

New preclinical data on odiparcil presented at MPS Society National Conference

In July Professor Chris Hendriksz (FYMCA Medical Ltd. and University of Pretoria, South Africa) will present 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.

Phase IIa iMProveS study to begin enrollment before year end 2017

Professor Hendriksz will also present details on the design of the planned Phase IIa iMProveS (improve MPS treatment) clinical study, which is expected to enroll its first patient before year end. 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.

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 Professor Paul Harmatz. The aim of the study is to recruit 21 subjects (12 with MPS VI and nine healthy volunteers) to determine whether assessment of GAG 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.

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.

ABBV-553 a phase I treatment for moderate to severe psoriasis in collaboration with AbbVie progressing in clinical development

Inventiva is currently collaborating with AbbVie to develop best-in-class oral small molecules that suppress the production of inflammatory cytokines that can cause moderate to severe psoriasis and other diseases currently treated by biologic agents. The most advanced drug candidate from this program, Abbv-553, a selective, potent and orally available RORγ inverse agonist, is now in Phase I clinical testing as a treatment for moderate to severe psoriasis. Inventiva is eligible to milestones and sales royalties.

Partnership with Boehringer Ingelheim to develop new treatments for idiopathic pulmonary fibrosis (IPF)

Inventiva has also entered into a drug discovery collaboration with Boehringer Ingelheim to validate a new therapeutic concept to treat idiopathic pulmonary fibrosis (IPF) and other fibrotic diseases. Target validation work under this collaboration is currently ongoing. Inventiva is eligible to milestones and sales royalties. The agreement with Boehringer Ingelheim provides for milestone payments linked to scientific milestones which could reach up to €170 million and for royalties on sales of products arising from the partnership.

"2017 so far has been a transformative year for Inventiva with progress made on clinical, financial and operational fronts. We completed a very successful IPO, listing on Euronext Paris, and in the process raised €48.5 million. We continue to advance our lead product candidate, IVA337, through Phase IIb clinical testing and evaluate its potential efficacy and safety as an oral treatment for fibrotic diseases including non-alcoholic steatohepatitis (NASH) and systemic sclerosis (scleroderma, or SSc)," said Frederic Cren, CEO and co-founder of Inventiva. *"We are moving rapidly to launch odiparcil into clinical testing as a treatment for MPS VI and prepare for pivotal studies if preliminary findings are positive. Our partnerships with AbbVie and Boehringer-Ingelheim are progressing well with key milestones expected in 2017 and 2018. Finally our successful IPO has given us the financial resources to put in place our clinical and preclinical strategy."*

Key News Flow and Expected Milestones

2017

- Obtain MPS VI orphan status designation for odiparcil in EU and the United States
- Complete enrollment in Phase IIb FASST study of IVA337 in patients with SSc
- Expand clinical trial sites for the Phase IIb NATIVE study of IVA337 in patients with NASH
- Report results of biomarker study for Odiparcil
- Begin enrolment for the Phase IIa iMProveS study of odiparcil in patients with MPS VI
- Receive first preclinical milestone payment from Boehringer-Ingelheim

2018

- Report results of Phase IIb FASST study of IVA337 in patients with SSc
- Complete enrollment in Phase IIb NATIVE study of IVA337 in patients with NASH
- Report results of Phase IIa iMProveS study of odiparcil in patients with MPS VI
- Receive second clinical milestone payment from AbbVie as ABBV-553 progresses in clinical development

Next investor conferences

- Société Générale Field Trip Healthcare and Bio, Paris, September 26
- KBC Biotech and Healthcare Conference, New-York, September 28

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, 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, 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 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.