

## Inventiva: acceleration of the clinical development activities and consolidation of the financial position in 2016

- ▶ Launch of IVA337 Phase IIb trial in NASH
- ▶ Initiation of ABBV-553 Phase I trial, the first clinical candidate resulting from the partnership with AbbVie
- ▶ New partnership agreement with Boehringer Ingelheim
- ▶ Successful IPO on Euronext Paris with €48.5m raised
- ▶ Cash position reached €24.8m (+2.3m vs 2015), before taking into account the IPO proceeds
- ▶ Significant newsflow momentum expected in 2017 and 2018

**Daix (France), March 27, 2017 – 7:30 am CET** - Inventiva, a biopharmaceutical company developing innovative therapies, particularly to treat fibrosis, provides a business update and reports its financial results for the year ended December 31, 2016.

### Main highlights and business overview

- Launch of the Phase IIb trial investigating IVA337 in NASH
- Patient recruitment for IVA337 Phase IIb trial in systemic sclerosis in line with the timetable announced
- Phase I/II clinical trial investigating IVA336 in Maroteaux-Lamy syndrome (MPS VI) in preparation
- Publication of the US patent covering the use of IVA336 for the treatment of MPS VI patients
- Initiation of ABBV-553 Phase I trial, the first clinical candidate resulting from the partnership with AbbVie
- New partnership agreement with Boehringer Ingelheim to develop new treatments for idiopathic pulmonary fibrosis

### Key financial information

- Successful IPO on Euronext Paris with €48.5m raised on February 15<sup>th</sup> 2017
- Cash position as of December 31<sup>st</sup> 2016 and before taking into account the IPO proceeds, of €24.8m, an increase of €2.3m compared with 2015
- Sales of €9.4m, an increase of 94% compared to 2015

### Key newsflow and expected milestones

#### 2017

- End of recruitment for the two Phase IIb trials in systemic sclerosis and NASH
- Recruitment of the first patient for the Phase I/II trial in MPS VI
- Milestone payments from the partnerships with AbbVie and Boehringer Ingelheim

#### 2018

- Results of IVA337 Phase IIb trial in NASH
- Results of IVA337 Phase IIb trial in systemic sclerosis
- Results of IVA336 Phase I/II trial in MPS VI

**Frédéric Cren, CEO and co-founder of Inventiva, said:** *“Our successful IPO on Euronext Paris – one of the largest in the sector with over €48 million raised – comes after an excellent 2016. The IPO proceeds strengthen an already positive cash position and will enable us to finance the development of our project portfolio.”*

*“2017 already looks like another year of strong achievements, in particular with the continuation of IVA337 clinical trials in NASH and systemic sclerosis, the recruitment of the first patient for IVA336 trial in MPS VI and the expected achievement of major milestones in our two collaborations with AbbVie and Boehringer Ingelheim,” added Pierre Broqua, CSO and co-founder of Inventiva.*

## Highlights and business overview

### Launch of the Phase IIb trial assessing IVA337 in NASH

Inventiva has launched the Phase IIb NATIVE clinical trial with IVA337 for the treatment of NASH, a severe fibrotic liver disease that affects more than 30 million people in the United States<sup>1</sup> with a market value estimated between \$35 billion and \$40 billion<sup>2</sup>. The study is a randomized, double-blind multicenter placebo-controlled clinical trial on patients suffering from NASH and will aim in particular to demonstrate the safety and efficacy of two doses of IVA337 (800 and 1,200 mg per day) over a period of 24 weeks. Up to 225 patients in 12 European countries will be recruited. The main assessment criterion will be the improvement in the histological component of inflammation and ballooning, without worsening of fibrosis. Patient recruitment is expected to be completed at the end of year, with results available in mid-2018.

### Recruitment for Phase IIb trial assessing IVA337 in systemic sclerosis in accordance with the timetable announced

Recruitment of patients suffering from systemic sclerosis (SSc) for the Phase IIb FASST trial is continuing with an inclusion rate in line with planning. SSc is a fatal orphan disease with no approved treatment, affecting around 170,000 people worldwide and representing an estimated market of over €1 billion in the United States<sup>4</sup>. FASST is a one year randomized double-blind study which will include a total of 132 patients in eight European countries receiving a placebo or one of the two doses of IVA337 being investigated. The study protocol approved by the European Medicines Agency (EMA) aims in particular to demonstrate for patients affected with the severe form of systemic sclerosis the beneficial effect of IVA337 on progression of the disease. Patient recruitment is expected to be completed at the end of the year, with the results available in the second half of 2018.

### Initiation of Phase I/II trial assessing IVA336 in Maroteaux-Lamy syndrome (MPS VI)

Inventiva has continued preparing the Phase I/II trial in MPS VI, a rare and serious genetic lysosomal disease in children caused by a deficiency of N-acetylgalactosamine-4-sulfatase (arylsulfatase B; ASB), which leads to an accumulation of glycosaminoglycans (GAGs) such as dermatan sulfate and chondroitin sulfate in the organs and tissues of patients, resulting in a large number of comorbidities. The life expectancy of MPS VI patients, if untreated, is approximately 20 years for patients with the severe forms of the disease and more for patients with the less severe forms<sup>3</sup>. Despite the availability of a substitute enzymatic treatment, there is still a significant medical need that may be met by IVA336. The disease affects around one live birth out of 225,000<sup>4</sup> worldwide and has been chosen as the first indication to demonstrate the efficacy of IVA336. The first patient for the iMProveS trial is expected to be recruited this year, with results due in mid-2018.

### Demonstration of the activity of IVA336 in an MPS VI model

Having demonstrated that IVA336 is able to reduce accumulation of intracellular GAGs in vitro in patients' cells and in vivo in an MPS model, new results obtained in an MPS VI transgenic mouse model mimicking the human pathology show that IVA336 reduces intracellular accumulation of GAGs in a number of organs and tissues not treated by enzyme replacement therapy and improves the animals' mobility.

<sup>1</sup>Angulo et al. Hepatology 1999; 30(6):1356-62. ; Minervini et al. J Hepatology 2009; 50:501-510.

<sup>2</sup>Market study by Deutsche Bank, 14 July 2014

<sup>4</sup>Corbus Investor Presentation; Cytori Therapeutics Investor Presentation

<sup>3</sup>Mucopolysaccharidoses, Rare diseases division of the Finnish Association of People with Physical Disabilities, 2013

<sup>4</sup>MPs society

**Strengthening of IVA336 intellectual property rights in the United States**

In February 2017 a patent protecting the use in the United States of IVA336 for the treatment of MPS VI was granted. With the patent granted in 30 European countries, Inventiva's exclusive use of IVA336 in all of its key markets is now secured until October 2034. Similar applications are currently being considered in around 20 other countries. In some countries (primarily in Europe, the United States and Japan), the life of patents could be extended by a maximum of five years in order to make up, if applicable, for the time needed to carry out clinical trials and obtain marketing authorization for IVA336. In addition, Inventiva has submitted other patent applications in Europe and the United States in order to protect the use of IVA336 for the treatment of other forms of mucopolysaccharidoses (MPS). These patent applications are currently under review.

**Initiation of the Phase I trial for ABBV-553, the first drug candidate stemming out from the partnership with AbbVie**

Inventiva with AbbVie have identified new orally active molecules inhibiting the ROR- $\gamma$  function for the treatment of many autoimmune diseases. A Phase I trial for the first drug candidate resulting from the collaboration - ABBV-553 – was initiated in 2016. Inventiva receives research funding and milestone payments and is eligible for royalty payments on sales.

**New partnership agreement with Boehringer Ingelheim to develop new treatments for idiopathic pulmonary fibrosis**

Inventiva signed a partnership agreement in May 2016 with Boehringer Ingelheim to validate a new target and discover new therapeutic molecules for the treatment of idiopathic pulmonary fibrosis (IPF) and other fibrotic disorders. Inventiva received an initial payment upon signing the partnership agreement and will also be able to receive research funding and milestone payments depending on progress made in research, development and reaching regulatory and commercial milestones, representing a total of up to €170 million. Inventiva will also be able to receive royalty payments at a variable rate on sales of products resulting from the partnership.

**Funding of €2.3m obtained for the YAP/TEAD research program**

The YAP/TEAD program identifies molecules blocking the interaction of YAP and TEAD, two transcription factors involved in a number of cancers including malignant mesothelioma and severe forms of lung, colon, ovarian and gastric cancer. In September 2016, Inventiva obtained two non-dilutive fundings for this research program worth a total of around €2.3 million. The first €1.5 million funding comes from the EUROSTARS program, a joint program between EUREKA and the European Commission to support SMEs presenting considerable technological potential involved in transnational collaborative projects, while the second €0.8 million comes from the French national research agency (ANR).

**2016 financial results****Sales of €9.4m increasing by 94% compared to 2015**

The company generated sales of €9.4 million during the year ended December 31, 2016, compared with €4.9 million in 2015, an increase of 94%. This growth is primarily due to two milestones being reached in the ABBV-553 ROR $\gamma$  program, as well as the signing of the partnership agreement with Boehringer Ingelheim.

**Spending under control and increase of R&D activities**

R&D expenditure amounted to €22.1 million increasing by 12.8%. Efforts continue to be focused primarily on external studies relating to the three clinical development programs. The company also strengthened in 2016 the internal resources of development department.

<i>Key figures (thousands of euros)</i> <i>IFRS – unaudited figures</i>	Period ended December 31	
	2016	2015
<b>Profit on ordinary activities</b>	<b>9,445.6</b>	<b>4,874.7</b>
Other recurring operating income	4,905.9	3,788.5
Research costs	(22,144.7)	(19,639.6)
Marketing –business development	(491.6)	(579.9)
General and administrative expenses	(3,764.2)	(3,318.3)
<b>Recurring operating profit (loss)</b>	<b>(12,048.9)</b>	<b>(14,874.7)</b>
Other non-recurring operating income	-	-
Other non-recurring operating expenses	(970.0)	(635.2)
<b>Operating profit (loss)</b>	<b>(13,018.9)</b>	<b>(15,509.9)</b>
Financial income	522.9	617.1
Financial expense	(62.7)	(131.0)
<b>Net financial items</b>	<b>460.2</b>	<b>486.1</b>
Income tax	5,513.6	6,200.4
<b>Net profit (loss)</b>	<b>(7,045.0)</b>	<b>(8,823.3)</b>

**Solid cash position of €24.8m at December 31, 2016, not taking into account the €48.5m raised during the IPO**  
 During the year, the company generated €2.3 million thanks to the growth in revenues, the continuing support from Abbott and the control of R&D expenses growth.

#### Successful IPO on Euronext Paris

Inventiva's IPO in February 2017 enabled the company to raise around €48.5 million by means of a capital increase, after partial exercise of the extension clause in the amount of 6.7% and of the over-allotment option in the amount of €0.5 million. This new equity financing will enable the company to fund all its activities until mid-2019.

#### Next financial announcement:

- **1<sup>st</sup> quarter 2017 sales:** Tuesday April 25, 2017(after market close)

#### Next investor conferences:

- Wainwright NASH Congress, New-York, April 3
- BioEquity Europe, Paris, May 22-23
- Société Générale Field Trip Healthcare and Bio, Paris, September 26
- KBC Biotech and Healthcare Conference, New-York, September 28

**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.

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, IVA336, which is a clinical program for the treatment of three different forms of mucopolysaccharidosis (MPS I or Hurler-Sheie syndrome, MPS II or Hunter syndrome and MPS VI also known as Maroteaux-Lamy syndrome), as well as a preclinical stage oncology portfolio.

Inventiva benefits from two partnerships with world-leading research entities such as the Institut Curie. Two strategic partnerships 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 these 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 (0)3 80 44 75 00

**NewCap**

Julien Perez /  
Mathilde Bohin  
Investor Relations  
[inventiva@newcap.eu](mailto:inventiva@newcap.eu)  
+33 (0)1 44 71 98 52

**NewCap**

Nicolas Merigeau /  
Arthur Rouillé  
Media Relations  
[inventiva@newcap.eu](mailto:inventiva@newcap.eu)  
+33 (0)1 44 71 94 98

**LifeSci Advisors**

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

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*Please refer to the « Document de Base » filed with the Autorité des Marchés Financiers on July 8, 2016 under n° I.16-066, and its update submitted on January 12, 2017 under n° D.16-0535-A01 for additional information in relation to such factors, risks and uncertainties.*

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