Boehringer Ingelheim and Inventiva collaborate to develop potential new treatments for idiopathic pulmonary fibrosis

- New collaboration to harness the therapeutic potential of a promising novel target for the treatment of Idiopathic Pulmonary Fibrosis (IPF)
- Total deal value up to €170 million, plus tiered sales royalties

Ingelheim, Germany and Daix, France, 31 May, 2016 – Boehringer Ingelheim and Inventiva, a French biopharmaceutical company specialized in the development of innovative therapies for fibrosis, oncology and orphan diseases, announced today, a new multi-year research and drug discovery collaboration and licensing agreement.

Under the terms of the agreement, the Inventiva and Boehringer Ingelheim research teams will jointly validate a new therapeutic concept with the aim of discovering new medicines for the treatment of Idiopathic Pulmonary Fibrosis (IPF) and other fibrotic diseases. The partnership will combine Inventiva’s deep knowhow and proprietary technologies in the field of transcriptional regulation and fibrosis with Boehringer Ingelheim’s capabilities in drug discovery and clinical development of new therapeutic agents.

The new collaboration is an example of Boehringer Ingelheim’s increasing focus on external innovation and builds on the company’s track record in IPF drug development. Boehringer Ingelheim has successfully developed nintedanib (OFEV®), a small molecule tyrosine kinase inhibitor, approved and marketed globally for the treatment of IPF in adults and will be responsible for clinical development and commercialization of potential drug candidates from the collaboration.

IPF is a debilitating and fatal lung disease with high mortality, affecting as many as 3 million people worldwide. It is characterized by chronic scaring and remodeling of the lung and progressive decline in lung function. IPF is the most common interstitial lung disease encountered worldwide and poses a major public health threat, as 70% to 80% of patients die within only 5 years from the diagnosis. To date, the cause of IPF is unidentified and despite recent progress treatment options for patients are still limited.

“We are very proud to enter into this collaboration with Boehringer Ingelheim, a company well-reputed for its excellent research and development skills in the field of fibrosis, and particularly
Idiopathic Pulmonary Fibrosis,” commented Inventiva’s co-founder and CSO Pierre Broqua. We plan, alongside developing our own pipeline, on pursuing our strategy of establishing collaborative research partnerships with the world’s biggest pharmaceutical companies. This new partnership further testifies to Inventiva’s expertise and contributes to strengthening our position as a leading and innovative actor in the field of fibrosis."

"We are enthusiastic about this partnership and look forward to collaborating with Inventiva’s team to develop a potential new breakthrough therapy for the treatment of Idiopathic Pulmonary Fibrosis,” concluded Clive R. Wood, Ph.D., Senior Corporate Vice President Discovery Research at Boehringer Ingelheim. “We are impressed by Inventiva’s research and drug discovery competencies and deep knowledge of the field. We firmly believe that joining forces with Inventiva will enable us to foster translation of an aspirational new therapeutic concept into eagerly awaited new therapies for patients."

Inventiva will receive an upfront payment and is eligible to receive research funding, potential research, development, regulatory and commercial milestone payments of up to €170 million and tiered royalties on net sales of the products resulting from the partnership. Full financial details remain undisclosed.

**About idiopathic pulmonary fibrosis**

IPF is a debilitating and fatal lung disease with high mortality, affecting as many as 3 million people worldwide. Progression of IPF is variable and unpredictable, and over time the lung function of an IPF patient gradually and irreversibly declines.

IPF causes permanent scarring or fibrosis of the lung, difficulty breathing and decreases the amount of oxygen the lungs can supply to major organs of the body. This is because over time, as the tissue thickens and stiffens with scarring, the lungs lose their ability to take in and transfer oxygen into the bloodstream. As a result, individuals with IPF experience shortness of breath, a non-productive cough and often have difficulty participating in everyday physical activities.

**About OFEV® (nintedanib)**

OFEV®, a small molecule tyrosine kinase inhibitor developed by Boehringer Ingelheim researchers, is indicated in adults for the treatment of IPF. In 2015 OFEV® was included in the updated international treatment guidelines for IPF.
OFEV® slows disease progression with approximately 50% reduction in the decline of lung function across a broad range of IPF patient types.\(^1\)\(^{3-9}\) This includes patients with early disease (minimal lung function impairment FVC >90% predicted),\(^6\) limited radiographic scarring (no honeycombing) on high resolution computed tomography (HRCT),\(^5\) and those with emphysema.\(^4\) Side effects with OFEV® can be effectively managed in most patients with diarrhea being the most frequently reported side effect.\(^3\)

OFEV® targets growth factor receptors, which have been shown to be involved in the mechanisms by which pulmonary fibrosis occurs.\(^1\)\(^{10}\) Most importantly OFEV® inhibits platelet-derived growth factor receptor (PDGFR), fibroblast growth factor receptor (FGFR) and vascular endothelial growth factor receptor (VEGFR).\(^10\)\(^{11-12}\) It is believed that OFEV® reduces disease progression in IPF and slows the decline in lung function by blocking the signaling pathways that are involved in fibrotic processes.\(^11\)\(^{-13}\)

**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 unique mechanism of action going through 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 IVA336, a clinical program for the treatment of three different forms of mucopolysaccharidosis (MPS I or Hurler-Schief syndrome, MPS II or Sly syndrome and MPS VI also known as Maroteaux-Lamy syndrome), as well as a preclinical stage oncology portfolio.

Inventiva benefits from partnerships with world-leading research entities such as the Institut Curie. A strategic partnership has also been put in place with AbbVie, making Inventiva eligible for preclinical, clinical, regulatory and commercial milestone payments, in addition to royalties on the products resulting from the partnership.
Inventiva employs over 100 highly qualified scientists and owns state-of-the-art R&D facilities near Dijon, acquired from the international pharmaceutical group Abbott. The Company owns, a proprietary library of over 240,000 molecules as well as integrated biology, chemistry and pharmacology platforms.

About Boehringer Ingelheim

Boehringer Ingelheim is one of the world's 20 leading pharmaceutical companies. Headquartered in Ingelheim, Germany, Boehringer Ingelheim operates globally through 145 affiliates and a total of some 47,500 employees. The focus of the family-owned company, founded in 1885, is on researching, developing, manufacturing and marketing new medications of high therapeutic value for human and veterinary medicine.

Social responsibility is an important element of the corporate culture at Boehringer Ingelheim. This includes worldwide involvement in social projects through, for example, the initiative “Making More Health” while also caring for employees. Respect, equal opportunity and reconciling career and family form the foundation of mutual cooperation. The company also focuses on environmental protection and sustainability in everything it does.

In 2015, Boehringer Ingelheim achieved net sales of about 14.8 billion euros. R&D expenditure corresponds to 20.3 per cent of net sales.

For more information please visit www.boehringer-ingelheim.com

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