

# Inventiva receives a €4 million milestone payment from AbbVie for cedirogant Phase IIb initiation

**Daix (France), Long Island City (New York, United States), January 31, 2022** – Inventiva (Euronext Paris and Nasdaq: IVA), a clinical-stage biopharmaceutical company focused on the development of oral small molecule therapies for the treatment of non-alcoholic steatohepatitis (NASH), mucopolysaccharidoses (MPS) and other diseases with significant unmet medical needs, today announced the receipt of a  $\leq$ 4 million milestone payment from AbbVie. It follows the inclusion of the first patient with psoriasis in the ongoing Phase IIb clinical trial with cedirogant (ABBV-157)<sup>1</sup>, an oral ROR $\gamma$  inverse agonist jointly discovered by Inventiva and AbbVie for the treatment of autoimmune diseases.

The Phase IIb clinical trial initiated by AbbVie with cedirogant is a multicenter, randomized, double-blind, placebocontrolled, dose-ranging study to evaluate the safety and efficacy of the drug candidate in adult patients with moderate to severe plaque psoriasis. The details of the clinical trial are available on clinicaltrials.gov<sup>2</sup>.

**Frédéric Cren, Chairman, Chief Executive Officer and cofounder of Inventiva, stated:** *"This new milestone payment and the initiation of a Phase IIb trial in adult patients with psoriasis are excellent news for Inventiva. It is an important step in the development of cedirogant, after the compound showed promising activity as an oral psoriasis agent in a Phase Ib clinical trial led by AbbVie. We are extremely proud to collaborate with AbbVie, a worldwide leader in autoimmune diseases, and we believe cedirogant has the potential to become a new reference treatment in psoriasis and other autoimmune diseases."* 

In 2012, Inventiva and AbbVie signed a multi-year drug discovery collaboration agreement to identify potent ROR $\gamma$  inverse agonists for the treatment of several auto-immune diseases. Through this collaboration, Inventiva leveraged its discovery expertise and technology platforms to develop drug candidates targeting the nuclear receptor ROR $\gamma$ , a validated drug target for the treatment of cutaneous inflammatory disorders such as psoriasis.

This collaboration with AbbVie enables Inventiva to receive payments upon the achievement of clinical, regulatory and commercial milestones, as well as tiered royalties on product sales, from mid single-digit to low double-digit.

## **About psoriasis**

Psoriasis is a common skin disease affecting more than 3% of the US adult population<sup>3</sup>. In moderate and severe cases, psoriatic lesions can be uncomfortable, itchy and disfiguring. Although the precise pathophysiology of psoriasis is unknown, an abnormal cutaneous immunologic/inflammatory response, associated with epidermal hyper proliferation and abnormal differentiation, seems to be involved.

Current treatment of psoriasis is directed toward the alteration of epidermal differentiation, reducing the inflammatory response and slowing the growth of involved skin cells. The extent and severity of the disease typically determine the therapeutic approach. In mild psoriasis, the most commonly used therapy is topical with the addition of phototherapy in refractory cases. In moderate to severe psoriasis, phototherapy or anoral systemic therapy are used.

<sup>&</sup>lt;sup>1</sup> <u>https://clinicaltrials.gov/ct2/show/NCT05044234</u>

<sup>&</sup>lt;sup>2</sup> https://clinicaltrials.gov/ct2/show/NCT05044234

<sup>&</sup>lt;sup>3</sup> Source : Armstrong et al., JAMA Dermatol. 2021;157(8):940-946. doi:10.1001/jamadermatol.2021.2007



### **About Inventiva**

Inventiva is a clinical-stage biopharmaceutical company focused on the development of oral small molecule therapies for the treatment of NASH, MPS and other diseases with significant unmet medical need.

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, as well as a deep pipeline of preclinical programs.

Lanifibranor, its lead product candidate, is being developed for the treatment of patients with NASH, a common and progressive chronic liver disease for which there are currently no approved therapies. In 2020, Inventiva announced positive topline data from its Phase IIb clinical trial evaluating lanifibranor for the treatment of adult patients with NASH and obtained both FDA Breakthrough Therapy and Fast Track designation for lanifibranor in the treatment of NASH. Lanifibranor is currently being evaluated in a pivotal Phase III clinical trial.

The Company has established a strategic collaboration with AbbVie in the area of autoimmune diseases resulting in the discovery of the drug candidate cedirogant (ABBV-157), an oral ROR $\gamma$  inverse agonist. Cedirogant showed promising activity as an oral psoriasis agent in a Phase Ib clinical trial and is currently being evaluated in a Phase Ib clinical trial in patients with moderate to severe chronic plaque psoriasis. This collaboration enables Inventiva to receive payments upon the achievement of pre-clinical, clinical, regulatory and commercial milestones, in addition to royalties on any approved products resulting from this collaboration.

Inventiva is also developing odiparcil, a second clinical stage asset, for the treatment of patients with subtypes of MPS, a group of rare genetic disorders. Inventiva announced positive topline data from its Phase IIa clinical trial evaluating odiparcil for the treatment of adult MPS VI patients in 2019 and received both FDA Fast Track and Rare Paediatric Disease designation for odiparcil in MPS VI.

In parallel, Inventiva is in the process of selecting an oncology development candidate for its Hippo signalling pathway program.

The Company has a scientific team of approximately 70 people with deep expertise in the fields of biology, medicinal and computational chemistry, pharmacokinetics and pharmacology, as well as in clinical development. It also owns an extensive library of approximately 240,000 pharmacologically relevant molecules, approximately 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 (ticker: IVA - ISIN: FR0013233012) and on the Nasdaq Global Market in the United States (ticker: IVA). www.inventivapharma.com

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## **PRESS RELEASE**



This press release contains forward-looking statements, forecasts and estimates with respect to Inventiva's clinical trials, clinical trial data releases, clinical development plans and anticipated future activities of Inventiva. 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 clinical trial results will be available on their anticipated timeline, that future clinical trials will be initiated as anticipated, or that candidates will receive the necessary regulatory approvals. 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, due to a number of factors, including that Inventiva is a clinical-stage company with no approved products and no historical product revenues, Inventiva has incurred significant losses since inception, Inventiva has a limited operating history and has never generated any revenue from product sales, Inventiva will require additional capital to finance its operations, Inventiva's future success is dependent on the successful clinical development, regulatory approval and subsequent commercialization of current and any future product candidates, preclinical studies or earlier clinical trials are not necessarily predictive of future results and the results of Inventiva's clinical trials may not support Inventiva's product candidate claims, Inventiva may encounter substantial delays in its clinical trials or Inventiva may fail to demonstrate safety and efficacy to the satisfaction of applicable regulatory authorities, enrollment and retention of patients in clinical trials is an expensive and time-consuming process and could be made more difficult or rendered impossible by multiple factors outside Inventiva's control, Inventiva's product candidates may cause adverse drug reactions or have other properties that could delay or prevent their regulatory approval, or limit their commercial potential, Inventiva faces substantial competition and Inventiva's business, and preclinical studies and clinical development programs and timelines, its financial condition and results of operations could be materially and adversely affected by the current COVID-19 pandemic. Given these risks and 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 Universal Registration Document for the year ended December 31, 2020 filed with the Autorité des Marchés Financiers on March 15, 2021, the Annual Report on Form 20-F for the year ended December 31, 2020 filed with the Securities and Exchange Commission on March 15, 2021 as well as the half-year financial report for the six months ended June 30, 2021 for additional information in relation to such factors, risks and uncertainties.

Except as required by law, Inventiva has no intention and is under no obligation to update or review the forwardlooking statements referred to above. Consequently, Inventiva accepts no liability for any consequences arising from the use of any of the above statements.