

Inventiva receives FDA Fast Track designation in MPS VI for its clinical-stage asset odiparcil

- ▶ The designation is intended to accelerate the regulatory review and facilitate the overall development of odiparcil for the treatment of MPS VI patients

Daix (France), October 19, 2020 – 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 need, today announced that the U.S. Food and Drug Administration (FDA) has granted Fast Track designation to odiparcil, the Company's clinical-stage drug candidate for the treatment of MPS type VI (MPS VI), a rare and progressive genetic disorder.

The Fast Track program of the FDA is designed to facilitate the development and expedite the regulatory review and potential approval of drug candidates. Its overall objective is to improve patient access to therapies aimed at treating serious conditions and filling significant unmet medical needs.

Pierre Broqua, Ph.D., Chief Scientific Officer and cofounder of Inventiva, commented: *"We are very pleased by the FDA's decision to grant Fast Track designation to odiparcil for the treatment of MPS VI. It is a clear recognition of the existing unmet medical need for this rare and progressive genetic disorder. We believe that odiparcil has the potential to become a treatment of choice for MPS VI patients, especially due to its oral formulation and ability to reach organs and tissues which are poorly treated by the current standard of care. This designation represents an important step in the development of odiparcil towards becoming an additional treatment for MPS VI patients, who are looking for more efficacious and convenient therapies."*

Fast Track designation offers the possibility of more frequent communication with the FDA to discuss the drug candidate's development plan, the design of the proposed clinical trials, the use of biomarkers, and the collection of appropriate data required to support drug approval. It also offers access to accelerated approval and priority review, as well as to rolling review of its Biologic License Application (BLA) or New Drug Application (NDA) on a section by section basis, rather than waiting for the entire BLA or NDA to be completed.

The Fast Track designation for odiparcil in MPS VI follows the acceptance by the FDA in August 2020 of Inventiva's Investigational New Drug (IND) application for odiparcil in the same indication and the publication at the end of 2019 of positive results from its iMProveS (*improve MPS treatment*) Phase IIa clinical trial evaluating odiparcil for the treatment of MPS VI adult patients.

About Fast Track designation¹

Fast Track is a process designed to facilitate the development and expedite the review and potential approval of drugs candidates to treat serious conditions and fill an unmet medical need. The purpose is to get important new drugs to the patient earlier. Fast Track addresses a broad range of serious and life-threatening conditions.

Determining whether a condition is serious is a matter of judgment, but generally is based on whether the drug will have an impact on factors such as survival, day-to-day functioning, or the likelihood that the condition, if left untreated, will progress from a less severe condition to a more serious one.

¹ <https://www.fda.gov/patients/fast-track-breakthrough-therapy-accelerated-approval-priority-review/fast-track>.

Filling an unmet medical need is defined as providing a therapy where none exists or providing a therapy which may be potentially better than available therapy. Any drug being developed to treat or prevent a condition with no current therapy is obviously directed at an unmet need. If there are available therapies, a fast track drug must show some advantage over available therapy, which is assessed against a pre-defined set of criteria.

About odiparcil

Odiparcil is an orally-available small molecule that acts on the underlying cause of the symptoms of mucopolysaccharidosis (“MPS”), a group of rare, progressive genetic disorders. MPS is characterized by the accumulation of glycosaminoglycans (“GAGs”), polysaccharides which are important for the modulation of cell to cell signalling and the maintenance of tissue structure and function, in the lysosomes of cells. Due to genetic mutations, lysosomes in patients with MPS contain deficient versions of the enzymes necessary to break down GAGs. As a result, GAGs accumulate within the lysosomes, causing the latter to swell and interfere with the ordinary functioning of cells, leading to the symptoms associated with MPS. MPS is categorized by subtypes, depending on the enzyme that is deficient and the corresponding GAGs that accumulate. By modifying how GAGs are synthesized, odiparcil facilitates the production of soluble GAGs that can be excreted in the urine, rather than accumulating in cells. Specifically, odiparcil acts on chondroitin sulfate (“CS”) and dermatan sulfate (“DS”), either or both of which accumulate in patients with MPS I, II, IVa, VI and VII.

Odiparcil has been evaluated for the treatment of MPS VI adult patients during the iMProVeS (*improve MPS treatment*) Phase IIa clinical trial with positive results published at the end of 2019.

Odiparcil has been granted Orphan Drug Designation (ODD) by the U.S. Food and Drug Administration (FDA) and the European Medicines Agency (EMA) and has also obtained Rare Pediatric Disease Designation (RPDD) in the U.S. for the treatment of MPS VI.

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 earlier stage 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. Inventiva recently announced positive topline data from its Phase IIb clinical trial evaluating lanifibranor for the treatment of patients with NASH.

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. At the end of 2019, Inventiva published positive results from its Phase IIa clinical trial evaluating odiparcil for the treatment of MPS VI adult patients.

In parallel, Inventiva is in the process of selecting an oncology development candidate for its Hippo signalling pathway program. Furthermore, the Company has established a strategic collaboration with AbbVie in the area of autoimmune diseases. AbbVie has started the clinical development of ABBV-157, a drug candidate for the treatment of moderate to severe psoriasis resulting from its collaboration with Inventiva. This collaboration enables Inventiva to receive milestone payments upon the achievement of pre-clinical, clinical, regulatory and commercial milestones, in addition to royalties on any approved products resulting from the collaboration.

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 (Euronext: IVA – ISIN: FR0013233012) and on the Nasdaq Global Market in the United States (ticker: IVA). www.inventivapharma.com

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Important Notice

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 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 undesirable side effects 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, 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 filed with the Autorité des Marchés Financiers on June 19, 2020 under n° D.20-0551 and its amendment filed on July 10, 2020 under n° D. 20-0551-A01 as well as the half-year financial report on June 30, 2020 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 forward-looking statements referred to above. Consequently, Inventiva accepts no liability for any consequences arising from the use of any of the above statements.