

Inventiva Announces End of Patient Recruitment for its Phase IIa Trial in the Treatment of MPS VI

- ▶ Last patient enrolled in the Phase IIa iMProveS trial evaluating odiparcil in MPS VI patients
- ▶ 20 patients included in the study, estimated as sufficient to identify first positive clinical signs and to impact relevant biomarkers
- ▶ First headline results expected by the end of the year

Daix (France), June 11, 2019 – Inventiva (Euronext: IVA), a clinical-stage biopharmaceutical company developing oral small molecule therapies for the treatment of diseases in the areas of fibrosis, lysosomal storage disorders and oncology, today announced the end of patient recruitment for its Phase IIa iMProveS (*improve MPS treatment*) trial in Europe evaluating odiparcil for the treatment of mucopolysaccharidosis type VI (MPS VI).

A total of 20 patients have been included in this Phase IIa trial versus an initial target of 24. Given odiparcil's mechanism of action, the Company believes that this number of patients is sufficient to evaluate odiparcil's safety profile and its impact on relevant efficacy biomarkers (measurement of glycosaminoglycans (GAGs) in the urine, skin and leukocytes) as well as to identify first signs of clinical efficacy in patients receiving enzyme replacement therapy (ERT) and in non-ERT treated patients. Therefore, Inventiva plans to amend the study protocol to update the target patient population to 20 subjects.

The patients included in the trial are distributed among the various arms, with fifteen patients being treated with ERT and receiving one of the two doses of odiparcil or placebo and five patients not being treated with ERT and only receiving the high dose of odiparcil. The headline results of the double-blind placebo controlled arms, which include the fifteen ERT-treated patients, are expected by the end of the year. Results of the open label cohort, which includes the five patients not being treated with ERT and only receiving the high dose of odiparcil, are expected during Q1 2020 given that the last patient for this subgroup was included in May 2019.

Marie-Paule Richard, M.D., Chief Medical Officer of Inventiva, stated: *"We are delighted to have achieved this number of very rare disease patients and we are grateful to them and the clinicians participating in this trial. MPS VI is an orphan, and very debilitating disease, with current treatment still leaving patients with high unmet medical needs. Odiparcil has the potential to improve clinical manifestations of the disease, especially in tissues and organs where the efficiency of current treatments is limited. Odiparcil's oral formulation could also be a great improvement for patients compared to current weekly infusions required for ERT. We look forward to obtaining the results of this Phase IIa trial to evaluate early signals of odiparcil's efficacy in the treatment of MPS VI and, if positive, to pursue its development."*

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 in the lysosomes of cells of glycosaminoglycans ("GAGs"), polysaccharides which are important for the modulation of cell-to-cell signaling and the maintenance of tissue structure and function. 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.

Inventiva is currently evaluating odiparcil in a Phase IIa clinical trial for the treatment of adult patients with the subtype MPS VI.

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 the Phase IIa iMProveS trial

The iMProveS (improve MPS treatment) study is a 26-week Phase IIa clinical trial taking place in four European sites and evaluating odiparcil for the treatment of patients with mucopolysaccharidosis (“MPS”) type VI. The primary endpoint of the trial is safety, as assessed by clinical and biological standard tests. Secondary endpoints include changes from baseline in leukocyte, skin and urinary glycosaminoglycan (“GAG”) content, improvements of activity and mobility, evaluation of cardiovascular, lung and respiratory function and vision and hearing impairments.

Patients enrolled are at least 16 years old. Patients receiving enzyme replacement therapy (ERT) and one of the two odiparcil tested doses or placebo are randomized in a double-blind placebo-controlled trial. Patients not being treated with ERT and only receiving the high dose of odiparcil are enrolled in an open label cohort.

About Inventiva

Inventiva is a clinical-stage biopharmaceutical company focused on the development of oral small molecule therapies for the treatment of diseases with significant unmet medical needs in the areas of fibrosis, lysosomal storage disorders and oncology.

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 – lanifibranor and odiparcil – in non-alcoholic steatohepatitis (“NASH”) and mucopolysaccharidosis (“MPS”), respectively, 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. Inventiva is currently evaluating lanifibranor in a Phase IIb clinical trial for the treatment of this disease for which there are currently no approved therapies.

Inventiva is also developing odiparcil, a second clinical stage asset, for the treatment of patients with MPS, a group of rare genetic disorders. The Company is currently investigating odiparcil in a Phase IIa clinical trial for the treatment of adult patients with the MPS VI subtype.

In parallel, Inventiva is in the process of selecting an oncology development candidate for its Hippo signalling pathway program. The Company has established two strategic partnerships with AbbVie and Boehringer Ingelheim in the areas of autoimmune diseases and idiopathic pulmonary fibrosis (“IPF”) respectively. AbbVie has started the clinical development phase of ABBV 157, a drug candidate for the treatment of moderate to severe psoriasis resulting from its collaboration with Inventiva. Both collaborations entitle 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 partnerships.

The Company has a scientific team of approximately 90 people with deep expertise in the fields of biology, medicinal and computational chemistry, pharmacokinetics and pharmacology. It also owns an extensive library of approximately 240,000 pharmacologically relevant molecules, around 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). www.inventivapharma.com

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Please refer to the “Document de référence” filed with the Autorité des Marchés Financiers on April 12, 2019 under n° R.19-006 for additional information in relation to such factors, risks and uncertainties.

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