Inventiva receives FDA Fast Track designation for lead asset lanifibranor in NASH

- Designation is intended to facilitate the development and expedite the regulatory review of lanifibranor for the treatment of NASH

Daix (France), September 26, 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 that the U.S. Food and Drug Administration (FDA) has granted Fast Track designation for the Company's lead product candidate, lanifibranor, for the treatment of non-alcoholic steatohepatitis (NASH).

The FDA's dedicated Fast Track program is designed to facilitate the development and expedite the review and potential approval of drug candidates. Its overall objective is to improve patient access to therapies intended to treat serious conditions and to fill significant unmet medical needs.

Pierre Broqua, Ph.D., Chief Scientific Officer and cofounder of Inventiva, commented: *"We are delighted that the FDA has granted Fast Track designation to lanifibranor for the treatment of NASH. It highlights the large and unmet medical need for this common, progressive and severe chronic liver disease, for which there is currently no approved therapy. We are convinced of the unique mechanism of action of lanifibranor, the only pan-PPAR agonist currently in development, and its potential to treat NASH patients. Today's decision represents an important step towards achieving our objective of getting appropriate therapy to patients as quickly as possible. We are pleased with the constructive and open dialogue we had so far with the FDA and we look forward to continue working closely together with them to accelerate the development of lanifibranor."*

Once a therapeutic product receives Fast Track designation, the respective company is eligible for 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 provides the respective company with accelerated approval and priority review, as well as rolling review meaning that the respective company can submit completed sections of its Biologic License Application (BLA) or New Drug Application (NDA) for review, rather than waiting until every section of the BLA or NDA is completed.

The FDA's decision follows the completion of patient recruitment for Inventiva's NATIVE (NAsh Trial to Validate IVA337 Efficacy) Phase IIb clinical study evaluating the drug candidate for the treatment of NASH. The study is progressing as planned and the publication of the results are expected in the first half of 2020. If positive, they will support the entry of lanifibranor into the pivotal Phase III trial, the last phase of its development prior to market launch.

About Fast Track designation[1]

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.

[1] https://www.fda.gov/patients/fast-track-breakthrough-therapy-accelerated-approval-priority-review/fast-track (12/09/2019).

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.

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 lanifibranor

Lanifibranor, Inventiva's lead product candidate, is an orally-available small molecule that acts to induce anti-fibrotic, anti-inflammatory and beneficial metabolic changes in the body by activating all three peroxisome proliferator activated receptor ("PPAR") isoforms, which are well characterized nuclear receptor proteins that regulate gene expression. Lanifibranor is a PPAR agonist that is designed to target all three PPAR isoforms in a moderately potent manner, with a well balanced activation of PPARα and PPARδ, and a partial activation of PPARγ. While there are other PPAR agonists that target only one or two PPAR isoforms for activation, lanifibranor is the only pan PPAR agonist in clinical development. Inventiva believes that lanifibranor's moderate and balanced pan PPAR binding profile contributes to the favorable safety and tolerability profile that has been observed in clinical trials and pre clinical studies to date.

Inventiva is currently evaluating lanifibranor in a Phase IIb clinical trial for the treatment of non-alcoholic steatohepatitis ("NASH"), a common and progressive chronic liver disease, for which there is currently no approved therapy.

About the NATIVE Phase IIb trial

The NATIVE (NAsh Trial to Validate IVA337 Efficacy) clinical trial is a 24-week randomized, double-blind, placebo-controlled Phase IIb clinical trial evaluating lanifibranor in the treatment of patients with non-alcoholic steatohepatitis ("NASH"). The goal of the trial is to assess the effect of lanifibranor on the improvement in liver inflammation and ballooning, which are two of the markers of the resolution of NASH. To be considered for inclusion, patients must have: a diagnosis of NASH confirmed by liver biopsy; a cumulative score of inflammation and ballooning (as measured using the steatosis, activity and fibrosis, or "SAF", scoring system) of three or four out of four, indicating the presence of moderate to severe inflammation and ballooning; a steatosis score greater than or equal to one; and a fibrosis score less than four, indicating the absence of cirrhosis. The primary endpoint of the trial is a reduction in the combined inflammation and ballooning score of two points compared to baseline, without worsening fibrosis. Secondary endpoints include NASH resolution, improvements of the steatosis, inflammation, ballooning and fibrosis scores from baseline as measured using the NAS and SAF scores, improvements of other fibrosis measures, improvements in several metabolic markers and safety.

The trial has randomized 247 patients with NASH at more than 70 sites in Australia, Canada, Europe, Mauritius and the United States. Results of the trial are expected in the first half of 2020.

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 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 70 people with deep expertise in the fields of biology, medicinal and computational chemistry, pharmacokinetics and pharmacology a well as in clinical development. 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

Contacts

Inventiva
Frédéric Cren
Chairman & CEO
info@inventivapharma.com
+33 3 80 44 75 00

Brunswick Group
Yannick Tetzlaff / Tristan Roquet
Montegon / Aude Lepreux
Media relations
inventiva@brunswickgroup.com
+33 1 53 96 83 83

LifeSci Advisors
Monique Kosse
Investor relations
monique@lifesciadvisors.com
+1 212 915 3820

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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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