Inventiva's iMProveS (improve MPS treatment) Phase IIa Clinical Study to start patient recruitment before year end

The biopharmaceutical company Inventiva aims to develop and provide patients with new therapies and is currently developing odiparcil as a new approach to treat several forms of mucopolysaccharidosis (MPS).

The orally-administrated small molecule odiparcil (formerly IVA336) was initially developed for the prevention of post-operative thrombosis and has so far been studied in over 700 healthy volunteers and 1100 patients in this indication. Odiparcil can increase the production of two circulating glycosaminglycans (GAGs), dermatan and chondroitin sulfate, of which dermatan sulfate inhibits thrombus formation without causing bleeding.

Odiparcil

the first oral treatment for MPS VI patients

After analysis of its mechanism of action, Inventiva discovered and demonstrated its potential in the treatment of several forms of MPS, in particular MPS I (Hurler/ Scheie syndromes), MPS II (Hunters syndrome) and MPS VI (Maroteaux-Lamy syndrome).

Unlike enzyme replacement therapy (ERT), odiparcil is well distributed to organs and tissues, which may improve the treatment of bone, joint and corneal lesions. It is able to reduce lysosomal accumulation in patients' cells by producing soluble glycosaminoglycans (GAGs) which can be then secreted outside the cells.

As a result of its unique mechanism, odiparcil by resolving the symptoms occurring in the eye, joints, cartilages and cardiac valves may address some of the so far unmet medical needs in MPS VI and become the first substrate replacement therapy in this indication.

Inventiva is engaged in a clinical program to validate the potential of odiparcil in MPS patients. The clinical program includes:

- a biomarker study in MPS VI patients;
- a phase IIa clinical study named iMProveS to investigate the safety and efficacy of odiparcil in MPS VI patients;
- a phase Ib study in children with MPS VI to investigate safety and pharmacokinetics ; and
- pivotal phase III clinical studies to obtain marketing approval for MPS I, II and VI.

iMProveS (improve MPS treatment) clinical study aims to investigate the safety, tolerability and efficacy of odiparcil in MPS VI patients. It is a 26-week phase IIa study, with 24 patients diagnosed with MPS VI, male or female of at least 16 years of age, with the exception of persons with coagulation deficiency and pregnant women. Patients receiving ERT on a regular basis and for more than 6 months will receive two doses of odiparcil (250 mg and 500 mg, two times a day) with ERT therapy versus a placebo. The study will also include an additional arm where six patients untreated by ERT will receive a 500 mg dose of odiparcil two times a day. The study is currently planned to run in two clinical centres in the UK and Germany from the fourth quarter of 2017.

In parallel to the iMProveS study, a short phase Ib study in children will be conducted mainly to determine the dose to be administered during the phase III.

If positive, the iMProveS study will allow Inventiva to initiate pivotal phase III trials in MPS I, II and VI

For information about the iMProveS trial please contact Mireille Tallandier at Inventiva (Mireille.tallandier@inventivapharma.com) or visit Inventiva's iMProveS web site www.improves-mpsvi-trial.com

iMProveS
IMPROVE MPS TREATMENT