

Masitinib is being investigated in the treatment of Amyotrophic Lateral Sclerosis (ALS)

45 patients were recruited in phase 2

Authorities have accepted the transformation of phase 2 into phase 3, with a prospective recruitment of 210 patients

AB Science SA (NYSE Euronext – FR0010557264 – AB), a pharmaceutical company specialized in research, development and marketing of protein kinase inhibitors (PKIs), announces the initiation of a clinical development program with masitinib in the treatment of Amyotrophic Lateral Sclerosis (ALS).

ALS is a rare degenerative disorder that results in progressive wasting and paralysis of voluntary muscles. There are approximately 30,000 people with ALS in the European Union (15,000 in the US) with more than 7,500 new cases developed each year (4,500 in the US). Almost 50% of ALS patients die within 3 years and 90% die within 5 years.

The clinical development program of masitinib in ALS started with a phase 2 clinical study, which involved the recruitment of 45 patients. Health authorities agreed to transform the phase 2 study into phase 3, with prospective recruitment of 210 patients. The readout of this study is expected by the end of 2015.

This study is a prospective, multicenter, randomized, double-blind, placebo-controlled, parallel groups, phase 3 study to compare the efficacy and safety of masitinib versus placebo in the treatment of patients suffering from Amyotrophic Lateral Sclerosis (ALS). Study treatment will be given as add-on therapy to patients who have been treated with a stable dose of riluzole. The study aims at evaluating the effect of masitinib on the functional impairment of patients assessed by Amyotrophic Lateral Sclerosis Functional Rating Scale (ALSFRS).

Professor Olivier Hermine, President of the scientific committee of AB Science explained: "In this study, we assume that mast cells, which are key immune cells, actively participate to the pathogenesis of ALS, through the release of mediators that sustain the inflammatory network of the central nervous system. Mast cells, which are present in large quantities in the brain and in the spinal cord, could also influence the survival and functions of motor neurons, and thus participate to the pathophysiology of ALS. Since masitinib is a selective inhibitor of c-Kit and Lyn, two kinases that play a major role in the survival and activation of mast cells, it may lead to positive effects on the symptoms of the pathology."

Alain Moussy, Chairman and CEO of AB Science commented: "Masitinib is already evaluated in other neurodegenerative indications such as Alzheimer's disease and multiple sclerosis. Through its original mechanism of action which targets mast cells and the inflammatory process, masitinib represents a potential innovative therapy in neurodegenerative diseases with significant unmet medical need."

About ALS

Essential features of ALS are progressive signs and symptoms of lower motor neuron dysfunction (atrophy, cramps, and fasciculations) associated with corticospinal tract signs (spasticity, enhanced and pathological reflexes). Even though the incidence of ALS is similar to that of multiple sclerosis, the prevalence is only 4-6/100,000 (about 25,000 patients in the United States), due to the higher mortality rate. The course is relentless with declines in strength, respiratory function and overall function during the active phase of the disease. No treatment prevents, halts or reverses the disease, although riluzole use is associated with a slight prolongation of survival.

About masitinib

Masitinib is a new orally administered tyrosine kinase inhibitor that targets mast cells, important cells for immunity, as well as a limited number of kinases that play key roles in various cancers. Owing to its novel mechanism of action, masitinib can be developed in a large number of conditions in oncology, in inflammatory diseases, and in certain diseases of the central nervous system. Through its activity of inhibiting certain kinases that are essential in some oncogenic processes, masitinib may have an effect on tumor regression, alone or in combination with chemotherapy. Through its activity on the mast cell and certain kinases essential to the activation of the inflammatory cells and fibrosing tissue remodeling, masitinib can have an effect on the symptoms associated with some inflammatory and central nervous system diseases.

About AB Science

Founded in 2001, AB Science is a pharmaceutical company specializing in the research, development and commercialization of protein kinase inhibitors (PKIs), a new class of targeted molecules whose action is to modify signaling pathways within cells. Through these PKIs, the Company targets diseases with high unmet medical needs (cancer, inflammatory diseases, and central nervous system diseases), in both human and veterinary medicines.

AB Science has developed a proprietary portfolio of molecules and the Company's lead compound, masitinib, has already been registered for veterinary medicine in Europe and in the USA, and is pursuing nine on-going phase 3 studies in human medicine in GIST, metastatic melanoma expressing JM mutation of c-Kit, multiple myeloma, mastocytosis, severe persistent asthma, rheumatoid arthritis, Alzheimer's disease and progressive forms of multiple sclerosis. The company is headquartered in Paris, France, and listed on Euronext Paris (ticker: AB).

Further information is available on AB Science website: www.ab-science.com.

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