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AB Science announces recruitment of first patient in phase 3 study of masitinib in progressive multiple sclerosis

AB Science SA (NYSE-Euronext, FR0010557264, AB), a pharmaceutical company specializing in the research, development and commercialization of protein kinase inhibitors (PKIs), announced today recruitment of the first patient in the phase 3 study of masitinib in primary progressive multiple sclerosis or relapse free secondary progressive multiple sclerosis.

This is an international, multicenter, randomized, double-blind, placebo-controlled, phase 3 study. Its objective is to compare the efficacy and safety of masitinib at 6 mg/kg/day with placebo in the treatment of patients with primary progressive multiple sclerosis or relapse free secondary progressive multiple sclerosis. This study will enroll approximately 450 patients, across 60 centers around the world, randomized with a ratio of 2:1 between the masitinib and placebo groups. The primary response evaluation will be the proportion of patients to achieve an improvement of at least 100% in their symptoms, as measured by the Multiple Sclerosis Functional Composite (MSFC) score, after 96 weeks of treatment.

Professor Patrick Vermersch (CHRU Lille - Hôpital Roger Salengro, France), the principal investigator of this study declared: *"Masitinib is a selective inhibitor of specific kinases that play a major role in the activation of mast cells, which are cells involved in the immune response, in the recruitment of lymphocytes to the brain, and also in inflammatory processes associated with multiple sclerosis and many of its resulting symptoms. Masitinib therefore represents an oral treatment different from those drugs already on the market for this indication, with a unique mechanism of action in blocking mast cells. In an experimental model of multiple sclerosis (mice immunized with myelin), masitinib demonstrated an ability to delay the onset of symptoms of multiple sclerosis. A phase 2 study of 30 patients in the two subpopulations of progressive multiple sclerosis, which represent approximately 60% of patients and for which there is no satisfactory treatment, has tested masitinib against placebo. The results showed that for the primary endpoint of MSFC (which measures symptoms of patients on three aspects: movement of the lower limbs, movement of the upper limbs, and cognitive tests) 30% of patients treated with masitinib were responders against 0% under placebo. Responses were seen in the third month and were more-or-less sustained over the study's 18-month duration. Masitinib therefore represents a promising new therapeutic approach in this disease, which justifies the initiation of this Phase 3 study."*

Professor Olivier Hermine, President of the scientific committee of AB Science commented: "*Masitinib differs from those treatments currently available or under development in multiple sclerosis. It has a weak immunosuppressive activity, although by inducing a reduction in the number of lymphocytes infiltrating the brain it helps prevent injuries. Masitinib's characteristic selectivity against mast cells also means that it is not associated to date with major toxicities; for example, cardiac toxicity as seen with mitoxantrone, a drug sometimes used in severe progressive multiple sclerosis, or opportunistic infections as seen with Tysabri or Gilenya, which are associated with an increased risk of infection."*

This phase 3 study is fully financed.

About multiple sclerosis

Multiple sclerosis is an inflammatory and neurodegenerative disease of the central nervous system. Commencing at an average age of 30 years (20-40 years) with a female preponderance, it is the leading cause of nontraumatic severe disability in young patients, and affects about 2.5 million people worldwide, including approximately 400,000 in the United States and 80,000 in France. Multiple sclerosis probably results from an interaction of genetic susceptibility

and one or more environmental factors including infectious agents such as viruses, the role of which has long been suspected but never proven. This manifests itself as an attack on the myelin sheath that surrounds the nerve fibers and acts to accelerate the flow of nerve impulses. Repeated inflammatory attacks will affect the functioning of these neural pathways by causing movement disorders (decreased muscle strength), sensory disturbances (change in the sensation of hot and cold, touch, tingling, etc.), balance disorders, visual disturbances and urinary problems.

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

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 its own portfolio of molecules including masitinib, which has already been registered in veterinary medicine in Europe and in the USA, and is pursuing nine phase-3 studies in human medicine, including seven studies on-going in pancreatic cancer, GIST, in metastatic melanoma expressing JM mutation of c-Kit, in mastocytosis, severe persistent asthma, rheumatoid arthritis, and in progressive forms of multiple sclerosis.

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

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