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Launch of a phase 3 clinical trial in the treatment of Alzheimer's disease with masitinib

First patients recruited in this study

AB Science SA (NYSE Euronext – FR0010557264 – AB), a pharmaceutical company specialized in research, development and marketing of protein kinase inhibitors (PKIs), announces the launch of a phase 3 clinical trial in the treatment of Alzheimer's disease with masitinib, as well as the recruitment of the first patients in this study in several countries.

This is an international, multicenter, randomized (1:1:1 ratio), double-blind, placebo controlled, three parallel group phase 3 study to compare the efficacy and safety of masitinib at two different doses in the treatment of patients with mild to moderate Alzheimer's disease. Study treatment will be given as add-on therapy to patients who have been treated for a minimum of 6 months with a stable dose of cholinesterase inhibitors (rivastigmine) and/or memantine, with no changes foreseen in therapy throughout the study.

The study aims at evaluating the effect of masitinib after 24 weeks of treatment on cognition and memory assessed by Alzheimer's Disease Assessment Scale (ADAS-Cog) and on self-care and activities of daily living assessed by Alzheimer's Disease Assessment Cooperative Study Activities on Daily Living (ADCS-ADL) at week-24.

This study, for which recruitment has started in Europe and other countries, will enroll approximately 400 patients.

As a reminder, masitinib is one of the few drugs that have generated significant efficacy results in phase 2 studies. In fact, the phase 3 study follows a phase 2 study, in which masitinib administered as an add-on therapy to standard care during 24 weeks showed promising signs of retarding the rate of cognitive decline of Alzheimer's disease as compared against placebo, with an acceptable tolerance profile. Improvement in cognitive function and functional capacity was seen in the masitinib treatment group, as evident through the sustained and statistically significant response in ADAS-Cog, as well as the mean change in ADAS-Cog and ADCS-ADL values relative to baseline. The phase 2 results have been published: Alzheimers Res Ther. 2011 Apr 19;3(2):16. doi: 10.1186/alzrt75.

Summary of the phase 2 study design and results

The objective of the double-blinded, randomized in parallel groups and placebo-controlled study was to evaluate masitinib, administered orally over 24 weeks, in patients suffering from mild-to-moderate Alzheimer's disease. Response was measured by change in ADAS-Cog, ADAS-ADL and MMSE scores after 24 weeks of treatment. A total of 35 patients were included in this study.

The rate of clinically relevant cognitive decline according to the primary endpoint, ADAS-Cog response (increase >4 points), was significantly lower with masitinib treatment compared to placebo after 12 and 24 weeks (6% versus 50% for both; p=0.040 and p=0.046, respectively). Moreover, whilst the placebo treatment-arm showed worsening mean ADAS-Cog, ADCS-ADL, and MMSE scores, the masitinib treatment-arm reported improvements, with statistical significance between treatment-arms at weeks 12 and/or 24

(respectively, p=0.016 and 0.030; p=0.035 and 0.128; and p=0.047 and 0.031). Adverse events occurred more frequently with masitinib treatment (65% versus 38% of patients); however, the majority of events were mild or moderate and transient.

About Alzheimer's disease

Alzheimer's disease is the most frequent neuro-degenerative disease in the world, affecting approximately 6% of people aged over 65 years, i.e. 850,000 people in France. The disease represents an important medical need. In fact, Alzheimer's disease is associated with an elevated risk of death. In the United States, Alzheimer's disease is the sixth-leading cause of death across all ages. Regardless of the cause of death, 61% of people diagnosed with Alzheimer's disease at age 70 are expected to die before age 80 compared with 30% of people at age 70 without Alzheimer's disease. In particular, the inability in late-stage Alzheimer's disease to move around can make a person more vulnerable to infections, including pneumonia which can be fatal.

Alzheimer's disease is characterized by the appearance of lesions that gradually invade and destroy brain neurons, resulting in progressive cognitive decline and memory. The two types of lesions are the amyloid deposits in the brain parenchyma (amyloid plaques) or blood vessels (amyloid angiopathy), and neurofibrillary tangles. Besides these lesions, inflammation contributes to alter neurons. No treatment which stops or reverses the disease process is available so far.

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 eight 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, and progressive 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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