Paris, 8 December 2015, 7pm

AB Science announces completion of patient recruitment for the phase 3 study of masitinib in amyotrophic lateral sclerosis (ALS)

Interim analysis is planned for Q1 2016

AB Science SA (NYSE Euronext – FR0010557264 – AB), a pharmaceutical company specialized in research, development and marketing of protein kinase inhibitors (PKIs), announces today that it has completed the targeted enrolment of 381 patients in the phase 3 study evaluating masitinib in the treatment of amyotrophic lateral sclerosis.

The interim analysis is expected in Q1 2016.

"We have completed active recruitment of patients in our phase 3 study in amyotrophic lateral sclerosis as per schedule" said Alain *Moussy, Chief Executive Officer of AB Science. "Cumulative evidence on masitinib's efficacy in ALS animal models and the underlying mechanism of action of masitinib based on its interaction with microglia and mast cells have contributed to the high level of recruitment and support from the medical community. The interim analysis will be a crucial milestone."*

On-going phase 3 in ALS

The study objective is to compare the efficacy and safety of masitinib plus riluzole with placebo plus riluzole. The primary endpoint is to measure the change in ALSFRS-R at week 48. The ALSFRS-R score is a validated rating instrument for monitoring the progression of disability in patients with ALS, which correlates significantly with quality of life and survival. This endpoint is recommended by EMA and FDA guidelines for registration in ALS.

The Independent Data Safety and Monitoring Committee (IDMC) previously recommended the continuation of this phase 3 trial based on safety analysis and based on the outcome of the futility test for efficacy.

The next step is an interim analysis that has been pre-specified in the protocol and that is planned in Q1 2016.

Study Rationale is based on the targeting of mast cell and microglia

A growing body of evidence suggests that ALS is a neurodegenerative disorder in which cross-talk between microglia, mast cells and astrocytes may destroy motor neuron cells.

Mast cells seem to play a central role in the inflammatory process of ALS. Several studies describe key mechanisms of action of mast cells in ALS:

- Mast cells infiltrate the spinal cord of ALS patients.
- Elevated TNF alpha levels, which are expressed through mast cells, have been reported in ALS patients and have been shown to induce motor neuron death.

Masitinib blocks mast cells activation and degranulation through three kinases: c-Kit, Lyn, and Fyn.

Glial cells play a pathogenic role in the progressive degeneration of motoneurons characteristic in ALS. In rats model of ALS (SOD1G93A mutation) the rapid spread of paralysis coincides with proliferating aberrant microglia, an astrocyte phenotype (AbA) surrounding motoneurons.

Masitinib targets proliferating AbA in culture by inhibiting the M-CSF (macrophage colony stimulating factor), as well as retarding cell migration and the expression of inflammatory mediators.

Remarkably, oral administration of masitinib started 7 days after disease onset prolonged post-paralysis survival by 40%, an unprecedented protective effect in ALS rat models. Masitinib also greatly reduced aberrant microgliosis and motoneuron pathology in the spinal cord in rat model.

Market potential

Amyotrophic lateral sclerosis 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 and 15,000 in the US, with more than 7,500 new cases diagnosed each year in Europe and 4,500 in the US. Almost 50% of ALS patients die within 3 years and 90% die within 5 years.

Orphan drug status

Masitinib received orphan drug designation for Amyotrophic Lateral Sclerosis from FDA.

About masitinib

Masitinib is a new orally administered tyrosine kinase inhibitor that targets mast cells and macrophages, important cells for immunity, through inhibiting a limited number of kinases. Based on its unique 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. In oncology due to its immunotherapy effect, masitinib can have an effect on survival, alone or in combination with chemotherapy. Through its activity on mast cells and microglia and consequently the inhibition of the activation of the inflammatory process, masitinib can have an effect on the symptoms associated with some inflammatory and central nervous system diseases and the degeneration of these 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 class of targeted proteins whose action are key in signaling pathways within cells. Our programs target only diseases with high unmet medical needs, often lethal with short term survival or rare or refractory to previous lines of treatment in cancers, inflammatory diseases, and central nervous system diseases, both in human and animal health.

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. The company is currently pursuing twelve phase 3 studies in human medicine in first-line and second-line GIST, metastatic melanoma expressing JM mutation of c-Kit, multiple myeloma, metastatic colorectal cancer, metastatic prostate cancer, pancreatic cancer, mastocytosis, severe asthma uncontrolled by oral corticosteroid, Alzheimer's Disease, progressive forms of multiple sclerosis, and amyotrophic lateral sclerosis. The company is headquartered in Paris, France, and listed on Euronext Paris (ticker: AB).

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

This document contains prospective information. No guarantee can be given as for the realization of these forecasts, which are subject to those risks described in documents deposited by the Company to the Authority of the financial markets, including trends of the economic conjuncture, the financial markets and the markets on which AB Science is present.

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