Paris, 29 September 2016, 5.45pm

Filing of masitinib in the treatment of amyotrophic lateral sclerosis (ALS) to the European Medicines Agency (EMA)

AB Science SA (NYSE Euronext – FR0010557264 – AB), a pharmaceutical company specialized in the research, development and marketing of protein kinase inhibitors (PKIs), announces today the acceptance and validation from the European Medicines Agency (EMA) of the filing of masitinib in the treatment of amyotrophic lateral sclerosis (ALS), also known as Lou Gehrig's disease, for conditional marketing authorization. The review process started on 12 September 2016.

Filing for the Marketing Authorization of masitinib in ALS was done on the basis of the positive results of the predefined interim analysis of the phase 2/3 study AB10015 (press release of April 11 2016). This filing was also done on the basis of preclinical data showing neuroprotective effect of masitinib in amyotrophic lateral sclerosis through targeting of microglial cells, published in the review Journal of Neuroinflammation (press release of July 11 2016).

On the basis of the interim analysis results, the Rapporteurs appointed by the EMA have recommended the filing of masitinib in combination with riluzole in the treatment of adult patients with amyotrophic lateral sclerosis (ALS) for conditional marketing authorization.

On the basis on these results, masitinib also received from European Medicines Agency (EMA) Committee for Orphan Medicinal Products (COMP) the Orphan Drug Designation and FDA approved first compassionate use of masitinib in amyotrophic lateral sclerosis.

The phase 2/3 study AB10015 was a double-blind, placebo-controlled study to compare the efficacy and safety of masitinib in combination with riluzole versus placebo in combination with riluzole in the treatment of patients suffering from amyotrophic lateral sclerosis (ALS). In accordance with study protocol, an interim analysis was planned to be performed once 191 patients (50% of the study population) had reached the 48-week treatment time point. The interim analysis primary endpoint was based on the change from baseline to week 48 in the revised Amyotrophic Lateral Sclerosis Functional Rating Scale (ALSFRS-R).
The interim analysis was designed to be a success if the pre-specified difference between treatment groups could be detected with a p-value below 0.0311.

The primary analysis was a success, with p-value < 0.01 in the intention-to-treat (ITT) population. All sensitivity analyses on the primary endpoint were also positive. The study was also successful on its secondary endpoints, FVC and CAFS. The frequency of adverse events (AEs), serious AEs, and AEs leading to discontinuation were similar between the two treatment arms.

EMA decision on registering masitinib in ALS should be known during the second half of 2017.

About Amyotrophic Lateral Sclerosis

Amyotrophic lateral sclerosis is a rare degenerative disorder that results in progressive wasting and paralysis of voluntary muscles. There are approximately 50,000 people with ALS in the European Union and in the US, with more than 16,000 new cases diagnosed each year in Europe and in the US. Almost 80% of ALS patients die within 5 years and 90% die within 10 years.

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 line of treatment in cancers, inflammatory diseases, and central nervous system diseases, both in humans 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, T-cell lymphoma, 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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