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AB Science Announces Positive Interim Results from Phase 3 Trial of Masitinib in Amyotrophic Lateral Sclerosis (ALS) (also known as Lou Gehrig's disease)

Company to Host Webcast on Masitinib in ALS in the Coming Days

AB Science SA (NYSE Euronext - FR0010557264 - AB), a pharmaceutical company specializing in the research, development and commercialization of protein kinase inhibitors (PKIs), today reports that a predefined interim analysis for its phase 3 randomized controlled trial evaluating masitinib in the treatment of amyotrophic lateral sclerosis has met its primary objective.

Study AB10015 was a double-blind, placebo-controlled phase 2/3 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 of 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 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. Secondary analyses included change from baseline to week 48 in Forced Vital Capacity (FVC), which is an indicator of the respiratory function, and Combined Assessment of Function (CAFS), which is another validated endpoint ranking patients based on survival time and change in ALSFRS-R score.

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.

A live webcast will be hosted in the coming days.

Alain Moussy, CEO and co-founder of AB Science said *"The positive outcome of this study in ALS is a significant milestone for the development of masitinib in neurology. We plan to share the data with EMA and FDA to discuss the possibility of filing an application for marketing authorization for masitinib in ALS".*

Professor Olivier Hermine, President of the AB Science Scientific Committee said: *"The non clinical data showed that masitinib was effective in animal models of ALS by blocking the proliferation of glia cells, thereby reducing motorneuron atrophy. The positive result from this clinical study demonstrates that this novel mechanism of action is relevant for the treatment of ALS in humans".*

Doctor Mora, international coordinator of the study said: *"Amyotrophic lateral sclerosis is a fatal neurodegenerative disease with a high unmet medical need. The challenge in treating ALS patients is underscored by the fact that there have been no drug advances for improving patient survival since the approval of riluzole over 20 years ago. The interim results from this masitinib phase 3, randomized trial are*

therefore very impressive and provide encouragement that we may soon have a new and more effective treatment option available, pending approval from regulatory agencies".

Targeted population with masitinib in ALS

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.

Orphan drug status

Masitinib received orphan drug designation for amyotrophic lateral sclerosis from FDA.

Study Rationale is based on the targeting of microglial cells and mast cells

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 neurons. Masitinib targets both mast cells and microglia and was shown to be capable of reducing death and atrophy of motoneurons in mice and rat models.

The scientific rationale of masitinib in ALS is based on the following features:

According to preclinical studies conducted by Dr Luis Barbeito's laboratory at the Montevideo Pasteur Institute, masitinib's primary mechanism of action is to regulate abnormal neuroglia activation through the inhibition of a receptor called CSF-1R. Through this target, masitinib is able to inhibit glial cell proliferation and activation, including aberrant phenotypes that induce motor neuron death.

As a secondary mechanism of action, masitinib acts on mast cells through the inhibition of the c-Kit/SCF and LYN/FYN signaling pathways. Consequently, masitinib is capable of modulating blood-brain barrier permeability and modulates also mast cell activity including mast cell–microglia cross-talk, leading to a reduction in release of inflammatory mediators.

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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