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AB Science announces that based on interim analysis, IDMC recommended the continuation of the masitinib phase 3 study in progressive forms of multiple sclerosis with no requirement to increase the study sample size

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 the Independent Data Safety Monitoring Committee (IDMC) recommended continuation of the phase 3 study evaluating masitinib in the treatment of primary progressive or relapse-free secondary progressive multiple sclerosis, with no Sample Size Reestimation (SSR) necessary.

Study AB07002 is a double-blind, randomized, placebo-controlled phase 3 trial designed to assess the safety and efficacy of masitinib in patients with primary progressive or relapse-free secondary progressive multiple sclerosis. The treatment period is 96 weeks. The primary efficacy endpoint is the change over 96 weeks in EDSS (Expanded Disability Status Scale), which is a scale used for quantifying disability in multiple sclerosis and monitoring changes in the level of disability over time.

The study recruitment was completed with 656 enrolled patients.

In accordance with study protocol, an interim analysis was planned to be performed once 50% of the study population had reached the 96 weeks treatment duration period. IDMC used the conditional power (predictive probability of success) calculation based on the primary endpoint to give its recommendation regarding study continuation and SSR.

Based on conditional power (CP) calculation using the current sample size, the IDMC recommended the continuation of the study with no reestimation of sample size meaning that according to the protocol, the predictive probability of success of the study is above 80% with the current sample size.

Additionally, the IDMC did not report any safety concern with masitinib in the study population.

The interim analysis was performed without any unblinding for the sponsor.

Final results of the study are expected in Q2 2019.

Targeted population

Four principal courses of MS are currently defined according to clinical characteristics; namely: Relapsing Remitting MS (RRMS), Secondary Progressive MS (SPMS), Primary Progressive MS (PPMS), and Progressive Relapsing MS (PRMS). The disease typically presents as RRMS, with more than 50% of RRMS patients entering a progressive phase (SPMS) following a highly variable delay. Approximately 10 to 15% of patients present with PPMS, which is characterized by continuous disease progression from the onset of disease, i.e. without relapses and remissions, for which prognosis is considered as poor due to the relatively rapid development of advanced disability as compared with RRMS.

Altogether, the progressive forms of multiple sclerosis represent around 60% of patients, hence around 400,000 patients in the USA and in the EU alone.

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 and is developed in twelve phase 3 indications in human medicine in metastatic prostate cancer, metastatic pancreatic cancer, relapsing metastatic colorectal cancer, relapsing metastatic ovarian cancer, GIST, metastatic melanoma expressing JM mutation of c-Kit, relapsing T-cell lymphoma, mastocytosis, severe asthma, amyotrophic lateral sclerosis, Alzheimer's disease and progressive forms of multiple 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.

Forward-looking Statements - AB Science

This press release contains forward-looking statements. These statements are not historical facts. These statements include projections and estimates as well as the assumptions on which they are based, statements based on projects, objectives, intentions and expectations regarding financial results, events, operations, future services, product development and their potential or future performance.

These forward-looking statements can often be identified by the words "expect", "anticipate", "believe", "intend", "estimate" or "plan" as well as other similar terms. While AB Science believes these forward-looking statements are reasonable, investors are cautioned that these forward-looking statements are subject to numerous risks and uncertainties that are difficult to predict and generally beyond the control of AB Science and which may imply that results and actual events significantly differ from those expressed, induced or anticipated in the forward-looking information and statements. These risks and uncertainties include the uncertainties related to product development of the Company which may not be successful or to the marketing authorizations granted by competent authorities or, more generally, any factors that may affect marketing capacity of the products developed by AB Science, as well as those developed or identified in the public documents filed by AB Science with the Autorité des Marchés Financiers (AMF), including those listed in the Chapter 4 "Risk Factors" of AB Science reference document filed with the AMF on November 22, 2016, under the number R. 16-078. AB Science disclaims any obligation or undertaking to update the forward-looking information and statements, subject to the applicable regulations, in particular articles 223-1 et seq. of the AMF General Regulations.

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