PRESS RELEASE

AB SCIENCE HAS RECEIVED APPROVAL FROM THE U.S. FOOD AND DRUG ADMINISTRATION (FDA) TO INITIATE THE CONFIRMATORY PHASE 3 STUDY WITH MASITINIB IN THE TREATMENT OF PROGRESSIVE MULTIPLE SCLEROSIS

Paris, December 29 2022, 6pm CET

AB Science SA (Euronext - FR0010557264 - AB) announced today that its Phase III clinical trial (AB20009) in progressive forms of multiple sclerosis has been approved by the US Food and Drug Administration (FDA).

This decision follows authorizations received from several European countries, including the French Agency (ANSM).

This approval to initiate a confirmatory study in neurology is the third obtained from the FDA after studies in Amyotrophic Lateral Sclerosis (AB19001) and Alzheimer's disease (AB21004).

Study AB20009 is actively recruiting patients. This is a randomized, double-blind, Phase 3 study to evaluate the safety and efficacy of masitinib 4.5 mg/kg/day in patients with primary progressive multiple sclerosis (PPMS) or non-active secondary progressive multiple sclerosis (nSPMS).

The study will enroll 800 patients from numerous study centers with Expanded Disability Status Scale (EDSS) score between 3.0 to 6.0 and absence of T1 Gadolinium-enhancing brain lesions. The primary endpoint of the study is the effect of masitinib on time to confirmed disability progression. The objective of this study is to confirm positive results from the phase 2B/3 study (AB07002). [1]

Masitinib is positioned in progressive forms of the disease (PPMS or nSPMS). Currently, there is only one approved treatment for primary progressive forms and none for non-active secondary progressive forms, which account for approximately 15% and 35% of MS cases respectively, approximately 500,000 patients in the US and Europe.

Masitinib targets microglia and mast cells, which are two cells of the innate immune system associated with the pathology of progressive MS. The mechanism of action of masitinib is different from and potentially complementary to other tyrosine kinase inhibitors being developed in multiple sclerosis, such as BTK inhibitors, which target B cells.

Professor Patrick Vermersch, MD, principal investigator of the study and Professor of Neurology at the University of Lille, France said: *"We are very pleased to receive FDA approval for this confirmatory study. This demonstrates interest from the health authorities in the masitinib program in progressive forms of multiple sclerosis and more broadly in neurodegenerative diseases, and also their acknowledgement that masitinib has viable neuroprotective role via its mechanism of action, which we believe is supported by the scientific and clinical data".*

[1] Vermersch P, Brieva-Ruiz L, Fox RJ, et al. Efficacy and Safety of Masitinib in Progressive Forms of Multiple Sclerosis: A Randomized, Phase 3, Clinical Trial. Neurol Neuroimmunol Neuroinflamm 2022;9:e1148. doi:10.1212/NXI.0000000000001148

About the results of the previous phase 2B/3 study AB07002

The study AB07002 met its primary analysis endpoint, demonstrating a statistically significant reduction in cumulative change on EDSS with masitinib 4.5 mg/kg/day (p=0.0256). This treatment-effect was consistent for PPMS and nSPMS. In addition, masitinib significantly reduced the risk of first disability progression by 42% and the risk of confirmed (3 months) disability progression by 37%. Masitinib also significantly reduced the risk of reaching an EDSS score of 7.0, corresponding to disability severe enough that the patient is restricted to a wheelchair (p=0.0093). The product's safety was consistent with the known risk profile of masitinib, with no elevated risk of infection, which may be an advantage over other drugs used in multiple sclerosis, many of which carry an increased risk of infectious complications.

About multiple sclerosis

Multiple sclerosis is an autoimmune disease of the central nervous system and the leading cause of non-traumatic neurological disability in young and middle-aged adults. Multiple sclerosis affects approximately 2.5 million people worldwide, including more than 100,000 people in France. It is characterized by a progressive degradation of the nerve cells of the central nervous system by the patient's immune system and comes in two main forms.

The relapsing-remitting form characterized by relapses of the disease. Relapsing-remitting multiple sclerosis includes secondary progressive active multiple sclerosis. During these relapses, patients experience the onset of new symptoms or the worsening of symptoms already present. These flare-ups are usually followed by recovery periods of varying length, after which some symptoms may persist. The relapsing-remitting forms of multiple sclerosis are mostly associated with dysfunctions of adaptive immunity (B cells and T cells).

The progressive form, characterized by a constant and regular worsening of the symptoms of the disease, without a distinct relapse or period of recovery. Progressive multiple sclerosis includes non-active secondary progressive multiple sclerosis The rate of onset of severe, disabling, and irreversible disability is much higher in the progressive forms of the disease than in the relapsing remitting forms. In progressive multiple sclerosis, innate immune cells such as macrophages, microglia or mast cells have been shown to probably play a major role.

A high medical need in progressive forms of multiple sclerosis

Patients with progressive forms of multiple sclerosis have a reduced life expectancy compared to the general population. The progressive worsening of neurological disability since the onset of the disease is associated with a significant reduction in quality of life and usually requires the use of a wheelchair for a large part of the patient's life. There is currently no cure for multiple sclerosis. The vast majority of registered therapies for multiple sclerosis that affect the course of the disease are only effective in relapsing forms of the disease (relapsing-remitting multiple sclerosis or active secondary progressive multiple sclerosis) and have not been shown to be effective in progressive forms of multiple sclerosis (primary progressive multiple sclerosis or non-active secondary progressive multiple sclerosis). There are currently no approved therapies for the population targeted by studies AB07002 and AB20009, i.e. non-active progressive MS.

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.

AB Science has developed a proprietary portfolio of molecules and the Company’s lead compound, masitinib, has already been registered for veterinary medicine and is developed in human medicine in oncology, neurological diseases, inflammatory diseases and viral diseases. 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 published by AB Science. 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.

For additional information, please contact:

AB Science
Financial Communication & Media Relations
investors@ab-science.com