PRESS RELEASE

AB SCIENCE RECEIVES U.S. FOOD AND DRUG ADMINISTRATION (FDA) AUTHORIZATION TO RESUME PATIENT ENROLMENT IN THE PHASE 3 STUDY OF MASITINIB IN AMYOTROPHIC LATERAL SCLEROSIS (ALS)

STUDY AB19001 HAS NOW BEEN AUTHORIZED IN 15 COUNTRIES IN EUROPE, USA, AND OTHER REGIONS AND IS ACTIVELY ENROLLING PATIENTS

Paris, 18 November 2021, 8.30pm CET

AB Science SA (Euronext - FR0010557264 - AB) today announced that it has received authorization from the United States Food and Drug Administration (FDA) to resume patient enrollment in the confirmatory Phase 3 study of masitinib (AB19001) in patients with amyotrophic lateral sclerosis (ALS).

Study AB19001 has been authorized in 15 countries in Europe, USA, and other regions and is actively enrolling patients.

Dr Christian Fassotte, Chief Medical Officer of AB Science said: "*We are delighted with this decision that will give US patients the opportunity to participate in this masitinib confirmatory trial. The previous phase 2/3 trial demonstrated that masitinib significantly slowed functional decline [1], with long-term follow-up analysis showing a significantly prolonged survival when masitinib is initiated at an early stage of disease [2]. It is therefore important that people living with ALS are given the opportunity to participate in this trial.*"

Study AB19001 is an international, multicenter, randomized, double-blind, placebo-controlled, 3-parallel group, Phase 3 study to compare the efficacy and safety of masitinib in combination with riluzole versus placebo in combination with riluzole for the treatment of people suffering from ALS.

The study is intended to confirm the previously published results from the first Phase 2b/3 study (AB10015), which demonstrated that masitinib at 4.5 mg/kg/day in combination with riluzole significantly slowed functional decline by 27% compared with riluzole alone at week 48, as measured by change in ALSFRS-R (Amyotrophic Lateral Sclerosis Functional Rating Scale-revised).

Study AB19001 recruitment targets people with ALS that have mild or moderate (non severe) impairment of functionality at baseline. This is closely aligned with the patient population that showed the greatest survival benefit with masitinib in the long-term survival analysis. The primary endpoint of study AB19001 is absolute change from baseline in functional score as assessed by ALSFRS-R after 48 weeks of treatment.

References

[1] Mora JS, Genge A, Chio A, et al. Masitinib as an add-on therapy to riluzole in patients with amyotrophic lateral sclerosis: a randomized clinical trial. Amyotroph Lateral Scler Frontotemporal Degener. 2020;21(1-2):5-14. doi:10.1080/21678421.2019.1632346

[2] Mora JS; Bradley WG; Chaverri D, et al. Long-term Survival Analysis of Masitinib in Amyotrophic Lateral Sclerosis. Ther Adv Neurol Disord 2021, Vol. 14: 1–16 doi:10.1177/ 17562864211030365

About amyotrophic lateral sclerosis

Amyotrophic lateral sclerosis (ALS) is a fatal motor neuron disorder that is characterized by progressive loss of the upper and lower motor neurons at the spinal or bulbar level. The disease belongs to a group of disorders known as motor neuron diseases, which are characterized by the gradual degeneration and death of motor neurons. In ALS, both the upper motor neurons and the lower motor neurons degenerate or die, and stop sending messages to muscles.

The prevalence of ALS in western countries is fairly uniform at 6 per 100,000 persons, corresponding to around 30,000 cases in Europe and 20,000 in the USA.

The first drug treatment for ALS, riluzole (Rilutek), was approved in 1995. In Europe, there has been no new treatment approved since riluzole.

About masitinib

Masitinib is a 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.

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.

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