



## PRESS RELEASE

### **AB SCIENCE ANNOUNCES THAT IT HAS RECEIVED THE FIRST AUTHORIZATION TO RESUME PATIENT ENROLLMENT IN THE PHASE 3 STUDY OF MASITINIB IN AMYOTROPHIC LATERAL SCLEROSIS (ALS)**

*Paris, 23 August 2021, 7.30pm CET*

**AB Science SA** (Euronext - FR0010557264 - AB) today announced that it has received the first authorization to resume patient enrollment in the confirmatory Phase 3 study of masitinib (AB19001) in amyotrophic lateral sclerosis (ALS).

This authorization from a national competent authority follows the submission of an amended protocol for the AB19001 study which includes a new risk management plan to strengthen cardiac safety.

This first authorization comes from a European national agency, namely Norway.

As a reminder, AB Science had made the decision on June 1<sup>st</sup> 2021 to temporarily suspend the enrollment of new patients in study AB19001.

AB Science expects to be able to progressively resume global enrollment during the month of September.

Therefore, the voluntary decision to suspend the enrollment of new patients will have resulted in a 3 months break in the enrollment schedule of the study.

#### **About studies AB19001 and AB10015**

As a reminder, 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 patients 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 Amyotrophic Lateral Sclerosis Functional Rating Scale-revised (ALSFRS-R) decline by 27% compared to riluzole alone at week 48 (p-value < 0.05).

Study recruitment targets people with ALS that have mild or moderate 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.

#### **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](http://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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