



## PRESS RELEASE

### MASITINIB RECEIVES ORPHAN DRUG STATUS FOR THE TREATMENT OF AMYOTROPHIC LATERAL SCLEROSIS (ALS) IN SWITZERLAND

Paris, December 27 2022, 7pm CET

**AB Science SA** (Euronext - FR0010557264 - AB) today announces that masitinib has been granted orphan drug status (ODS) by the Swiss Agency for Therapeutic Products (Swissmedic) for the treatment of patients with amyotrophic lateral sclerosis (ALS).

As a reminder, masitinib has previously received ODS for ALS from the U.S. Food and Drug Administration (FDA) and from the European Medicines Agency (EMA).

This designation provides the sponsor with a series of incentives, including:

- the possibility of a simplified authorization procedure (Art.13) by Swissmedic
- fee waivers, and
- extended document protection period of 15 years.

Orphan drug designation in Switzerland is given to compounds that are developed for the treatment of a life-threatening or chronically disabling disease that affects no more than 5 out of 10,000 persons in Switzerland, or its active substance has been recognized as an important medicinal product for rare diseases in another country with equivalent medicinal product control as stipulated in Art. 13 TPA.

Professor Olivier Hermine, President of the Scientific Committee of AB Science and member of the Académie des Sciences in France, said: *"We are pleased to be granted orphan drug status for masitinib from Swissmedic. This represents another important step in our progress and commitment to provide a new treatment option to ALS patients internationally"*.

#### **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.

#### **About masitinib**

Masitinib is an 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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