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## **AB Science provides update on EU marketing authorization application for masitinib in the treatment of amyotrophic lateral sclerosis**

**AB Science SA** (NYSE Euronext – FR0010557264 – AB), a pharmaceutical company specialized in research, development and marketing of protein kinase inhibitors (PKIs), announces its decision not to pursue the re-examination procedure that the company initially requested for the marketing authorization application of masitinib in the treatment of amyotrophic lateral sclerosis (ALS). AB Science determined that the re-examination procedure would not be the most appropriate format to address all the pending concerns raised by the Committee for Human Medicinal Products (CHMP). AB Science will discuss with EMA the pathway forward to seek marketing authorization for the use of masitinib in the treatment of ALS.

The marketing authorization application was filed in September 2016 based on the interim results from study AB10015. The final safety data were generated in February 2018 and could not be inspected during the evaluation. New data cannot be presented as part of a reexamination procedure.

AB Science is therefore evaluating the possibility to resubmit the application based on the final results from study AB10015. As part of the resubmission, AB Science intends to submit:

- Final safety data.
- New sensitivity analyses on the primary analysis of the ALSFRS-R score for patients who stopped the study prematurely, applying recommended methods as per EMA guidelines in order to corroborate the results based on the LOCF method (last observation carried forward).
- New preclinical data reinforcing the mechanisms of action of masitinib, which is an important consideration in the context of an application based on a single pivotal trial.

AB Science reaffirms its commitment to carry out the development of masitinib in ALS in order to provide a new treatment option to ALS patients.

Amyotrophic lateral sclerosis is a rare degenerative disorder that results in wasting and progressive paralysis of muscles. There are approximately 50,000 people with ALS in the European Union and in the US, with more than 16,000 new cases diagnosed each year in Europe and in the US. This disease has a fatal outcome for most patients within 5 years from diagnosis.

### **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](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 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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