

# AB SCIENCE ANNOUNCES THE VALIDATION OF ITS RISK MANAGEMENT PLAN BY THE FRENCH NATIONAL AGENCY (ANSM) IN ORDER TO RESTART PATIENT ENROLLMENT IN FRANCE

Paris, July 12, 2021, 8am

AB Science SA (Euronext - FR0010557264 - AB) announced today that it has been informed by the French National Agency (ANSM) that the measures proposed by AB Science to reinforce patient safety in masitinib trials are acceptable to allow resumption of enrollment in its three ongoing studies; namely, the phase 3 study in mastocytosis (AB15003), the phase 3 study in amyotrophic lateral sclerosis (AB19001), and the phase 2 study in COVID-19 (AB20001).

These measures include the following changes for each of the aforementioned clinical studies:

- Strengthening of patient eligibility criteria to exclude individuals with a history of severe cardiovascular disease
- Reinforcement of tests to monitor cardiac function during the study
- Request for systematic advice from the Data and Safety Monitoring Board (DSMB) on the conduct of each study with respect to the risk of cardiovascular events
- Implementation of a committee composed of independent experts to assess all major adverse cardiovascular events

AB Science will update the clinical trial protocols with these additional measures and will submit a request to ANSM for authorization to resume enrollment for each of the studies concerned.

AB Science will also request without delay the resumption of its ongoing studies to other national competent authorities.

Dr Christian Fassotte, Chief Medical Officer of AB Science said: "The safety of patients included in our studies is our primary concern. We are delighted that the safety analysis produced by AB Science and the measures proposed to strengthen patient safety will allow for the restart of our studies".

### **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.

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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