



## PRESS RELEASE

### **AB SCIENCE ANNOUNCES THAT IT HAS SUBMITTED ITS RESPONSE TO THE DAY 120 QUESTIONS IN THE EMA REGULATORY REVIEW OF MASITINIB IN AMYOTROPHIC LATERAL SCLEROSIS AND CLARIFIES THE NEW TIMELINE FOR RESPONDING TO HEALTH CANADA**

*Paris, April 4 2023, 6pm*

**AB Science S.A.** (the "**Company**" - Euronext - FR0010557264 - AB) today provides an update on the schedule for the evaluation by the Committee for Medicinal Products for Human Use (CHMP) of the European Medicines Agency (EMA) and by Health Canada of its applications for conditional approval of masitinib in the treatment of amyotrophic lateral sclerosis (ALS).

As part of the ongoing EMA procedure, AB Science has submitted its responses to the Day 120 assessment of the procedure.

Because EMA and Health Canada regulatory procedures were concurrent and in order to ensure the best quality of responses in both procedures, AB Science, in agreement with Health Canada, has extended the response period to Health Canada by 30 days. The new deadline to respond to Health Canada is April 12, 2023.

AB Science has received support from several ALS patient groups in Canada and Europe for the conditional registration of masitinib in ALS.

Olivier Goy, co-founder and president of October, a European FinTech, said: *"Masitinib is one of the most promising drugs in ALS that has just been submitted to the EMA conditional approval process. I strongly support drugs that are submitted for conditional approval, especially when they have complementary mechanisms of action."*

Sabine Turgeman, Executive Director of the ARSLA (Association pour la recherche sur la SLA) said: *"The European regulation has provided since 2004 a legislative framework, in Article 14-a of Regulation (EC) No. 726/2004, to support the conditional registration of drugs in incurable diseases when definitive evidence of efficacy is not yet fully met. Conditional registration is the right procedure to accelerate access of new treatments to patients. We urge the EMA to apply maximum regulatory flexibility in the context of ALS, an incurable and fatal degenerative disease."*

Bre Hamilton, Executive Director of ALS Action Canada said: *"Marketing authorization under NOC/c status will allow Health Canada to provide earlier market access for Canadian living with ALS to products that have demonstrated promising clinical efficacy in clinical trials for the treatment, prevention or diagnosis of serious, life-threatening or severely debilitating diseases. Canadian families living with the devastating disease of ALS and in urgent need of new drug therapies want masitinib to benefit from this conditional registration."*

#### **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.

### **AB Science**

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