



**AB SCIENCE ANNOUNCES THAT HEALTH CANADA HAS RESUMED ITS REVIEW OF THE NEW DRUG SUBMISSION FOR MASITINIB IN AMYOTROPHIC LATERAL SCLEROSIS, FOLLOWING ISSUANCE OF A SCREENING ACCEPTANCE LETTER**

*Paris, 09 May, 2023, 6pm CET*

**AB Science SA** (Euronext - FR0010557264 - AB) today announces that Health Canada has issued a screening acceptance letter for the application of masitinib in the treatment of amyotrophic lateral sclerosis (ALS), meaning that the information and materials submitted by AB Science in response to the Notice of Deficiency (NOD) previously issued by Health Canada have been screened and found acceptable for the New Drug Submission to resume.

This letter is an important step in the procedure and effectively marks the restart date of the application's review by Health Canada. Indeed, once the Response to a NOD is screened and found acceptable for scientific review, a new review period begins immediately.

Under the NOC/c policy, Health Canada has a target of 200 calendar days maximum to review the application.

As a reminder, Health Canada issued in December 2022 a notice of deficiency (NOD) for the New Drug Submission of masitinib in the treatment of amyotrophic lateral sclerosis, meaning that Health Canada requested the provision of additional information. AB Science submitted its revised application in April 2023, which has now been found acceptable for scientific review.

The application includes new analysis, recently presented at the *American Academy of Neurology (AAN) 2023 Annual Meeting* in Boston, performed in ALS patients prior to any complete loss of physical function (corresponding to a score of 0 on any ALSFRS-R individual component and regardless of baseline progression rate and accounting for about 80% of the overall AB10015 study population), showing a statistically significant 18.4% relative benefit on the CAFS endpoint in favor of masitinib 4.5 mg/kg/day as compared with control ( $p=0.035$ ). The composite endpoint of functioning and survival (CAFS) is recommended by FDA and Health Canada as a primary endpoint to evaluate efficacy in ALS trials.

Alain Moussy, co-founder and CEO of AB Science, said: *"There is an urgent need expressed by ALS patients and their families in Canada to access masitinib treatment under NOC/c status and we will continue to work diligently with Health Canada to respond to this need."*

An estimated 3,000 Canadians are currently living with ALS. Each year approximately 1,000 Canadians die from ALS. A similar number of Canadians are diagnosed with ALS each year.

**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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#### **AB Science**

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