



**AB SCIENCE ANNOUNCES THAT HEALTH CANADA HAS GRANTED ELIGIBILITY FOR RECONSIDERATION REQUEST FOR MASITINIB IN AMYOTROPHIC LATERAL SCLEROSIS**

*Paris, 3 April, 2024, 6pm CET*

**AB Science SA** (Euronext - FR0010557264 - AB) today announces that Health Canada has granted eligibility for reconsideration request for masitinib in amyotrophic lateral sclerosis (ALS). The reconsideration process will re-examine, with new assessors, the decision based on information that was included in the original submission.

A Notice of Deficiency-Withdrawal (NOD/w) was issued on February 19, 2024 by Health Canada regarding the New Drug Submission (NDS) for masitinib in the treatment of ALS. The intention to submit a reconsideration request was based on the arguments summarized in the press release dated 26 February 2024.

Health Canada and AB Science have held a meeting to discuss the reconsideration process. AB Science is working closely with the agency to facilitate the review of masitinib conditional approval in ALS. AB Science has 45 days to file the reconsideration request.

The pivotal argument is on the treatment of missing data. Various sensitivity analyses show that study AB10015 was successful at week 48 when masitinib missing data are imputed as a placebo, which is recognized as a highly conservative methodology for missing data imputation (i.e., jump-to-reference). Rerandomization calculation, which ignores whether the data distribution is linear or not, was also successful. Furthermore, the Combined Assessment of Function and Survival (CAFS) analysis showed a p-value of 0.078, even though study AB10015 was not powered for this endpoint. A related time-to-event endpoint, Progression Free Survival (PFS), did show significant improvement in favor of masitinib. Additionally, in the subgroup of patients with 'ALS prior to any loss of function', a logically defined cohort based on masitinib's mechanism of action, a long-term median overall survival (OS) benefit of +22 months ( $p=0.0192$ ) was observed.

Professor Albert Ludolph, MD, PhD, Medical Director of the Neurology Department of at the University of Ulm, and principal investor of masitinib confirmatory study in ALS commented that, *"The recent failure of numerous phase 2 or 3 programs, including registered drugs such as AMX0035 (Amylyx) and oral edaravone (Ferrer), as well as investigational drugs such as TUDCA (the TUDCA-ALS consortium), reldesemtiv (Cytokinetics) and the RIPK1 inhibitor SAR443820 (Sanofi), have dashed the community's hopes of benefiting from new therapeutic advances and have effectively set us back with riluzole being the only treatment with a proven modest effect in the overall ALS population. We should learn from these failures. First, that demonstration of efficacy over a 24-week period is not predictive of efficacy over a 48-week period, which is the adequate duration to demonstrate a disease modifying effect in ALS. Second, that a 48-week study inevitably generates a large number of missing data. This situation is not unique to masitinib. It is a real challenge in the evaluation of efficacy and we are at risk of overlooking promising compounds. Masitinib has published results over a 48-week period, positive when appropriate methodology to treat missing data is applied, and it deserves careful consideration"*.

**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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