PRESS RELEASE

AB SCIENCE PROVIDES AN UPDATE ON THE APPLICATION FOR CONDITIONAL MARKETING AUTHORISATION OF MASITINIB IN THE TREATMENT OF AMYOTROPHIC LATERAL SCLEROSIS

Paris, 17 October, 2024, 7.30pm CET

AB Science SA (Euronext - FR0010557264 - AB) today announces that the European Medicines Agency (EMA) confirmed a negative opinion for the conditional marketing authorization of masitinib in the treatment of amyotrophic lateral sclerosis (ALS), following a vote adopted during the Committee for Medicinal Products for Human Use (CHMP) meeting on 14-17 October 2024. The Conditional Marketing Authorization of masitinib had been under review by the CHMP in response to the company's request for a re-examination of the negative opinion issued in June 2024.

Despite the difficulty of a conditional marketing authorization in ALS, AB Science had asked for a re-examination first and foremost considering the urgent need for patients to have early access to a promising treatment and the clinical data obtained from the first study AB10015, showing an increase in median overall survival of + 6 months (p= 0.0761) in the primary analysis population of Normal progressors, and a significant + 12 months survival benefit (p=0.0192) in a subgroup defined as patients prior to any complete loss of function (i.e. excluding patient with an ALSFRS-R score of 0 in any of the 12 items of the scale).

A Scientific Advisory Group – Neurology (SAG-N) was conveyed for the first time, as part of the re-examination procedure. Importantly, the SAG-N experts agreed with the categorization approach to distinguish between Normal and Fast Progressors (and with the 1.1 points per month ALSFRS decline from onset as cut-off), if properly pre-specified. This opinion supports the design of the confirmatory study of masitinib in ALS, as the same dichotomization and the same cut-off have been pre-specified for the confirmatory study.

The phase 2B/3 study AB10015 is considered hypothesis generating but not sufficient as a single pivotal study to support a marketing authorization.

Separately, Health Canada recently informed AB Science that key analyses presented for the reconsideration submitted in May 2024 [1], have been considered as new data, rather than re-analyses of existing data. Considering that Health Canada guideline prevent the use of new data as part of the re-examination procedure, AB Science has decided to notify Health Canada it will not pursue the reconsideration. Health Canada has offered the possibility to submit a new application to resolve this issue.

Alain Moussy, CEO and co-founder of AB Science said "*We are thankful to the patients and physicians that supported the re-examination process as part of the EMA review. We did all these efforts for the patients. We are convinced that masitinib is a promising drug when we see patients from the study surviving with the drugs for more than 10 years in our compassionate use program. Now AB Science objective is to focus on the confirmatory phase 3 program of masitinib in ALS to reach full approval*".

References

[1] AB Science press release dated 3 April 2024

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
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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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