PRESS RELEASE

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

Paris, 28 June, 2024, 12:30pm CET

AB Science SA (Euronext - FR0010557264 - AB) today announces that the Committee for Medicinal Products for Human Use (CHMP) of the European Medicines Agency (EMA) has adopted, in line with the trend vote, a negative opinion on the application for conditional marketing authorization of masitinib in the treatment of amyotrophic lateral sclerosis (ALS).

AB Science intends to ask for re-examination on the basis of:

1) First and foremost, the urgent need for patients to have early access to a promising treatment.
2) The opportunity of having the dossier re-examined by new rapporteurs and by a Scientific Advisory Board.

AB Science highlights the difficulty of a conditional marketing authorization in ALS and cannot guarantee a positive outcome following this re-examination.

The grounds to request a re-examination could be based on the following elements:

- Acceptable masitinib safety: First, the CHMP confirmed that the safety of masitinib is deemed acceptable, which is a key consideration in the context of a conditional marketing authorization where confirmatory evidence of efficacy is required.
- Objection concerning deviations from Good Clinical Practice: As per EMA guidance (EMA/868942/2011), impact analyses of all protocol deviations that could not be corrected were performed and showed no impact, resolving Good Clinical Practice issues as per guideline.
- Objection concerning the exclusion of fast progressors: The amendment transitioning from phase 2 to phase 3 excluding fast progressors from the primary analysis population was necessary and well justified, in order to have a more homogenous population with greater chance of reaching week 48 time point and minimizing missing data. Furthermore, the amendment was implemented early enough and while the study was blinded, removing any methodological issues.
- Objection concerning the treatment of missing data in the primary analysis: Multiple sensitivity analysis of the primary analysis; using non LOCF (*Last Observation Carried Forward*) methods for imputation of missing data, are positive and consistent, including two analyses previously recommended by the CHMP, demonstrating the robustness of the primary analysis, thus resolving the objection concerning the treatment of missing data.
- Objection on the subgroup data: There was an important imbalance in a subset of patients experiencing complete loss of function (i.e., ALSFRS-R score of zero) in one or more of the item scores (20% in the masitinib arm versus 8% in the placebo arm), because ALSFRS-R score was minimized but not stratified by category of severity. The subgroup defined as patients prior to any complete loss of function (i.e. excluding the overmentioned biased subset) accounted for 86% of the population and showed extremely compelling results, including a significant 12 months survival benefit. The subgroup analysis is the strict application of EMA guidance (EMA/CHMP/539146/2013), which is applicable to post hoc analysis and to registration with single pivotal study, thus resolving the objection regarding subgroup data.

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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