



AB SCIENCE PROVIDES AN UPDATE ON THE EUROPEAN MEDICINES AGENCY'S TIMETABLE FOR EXAMINATION OF THE MARKETING AUTHORIZATION APPLICATION OF MASITINIB IN AMYOTROPHIC LATERAL SCLEROSIS

BASED ON THE UPDATED TIMETABLE, A DECISION FROM THE EUROPEAN MEDICINES AGENCY IS EXPECTED DURING THE FIRST QUARTER OF 2024

Paris, 18 September, 2023, 6pm CET

AB Science SA (Euronext – FR0010557264 – AB) today provided an update on the European Medicines Agency's (EMA) Committee for Medicinal Products for Human Use (CHMP) timetable for examination of the masitinib marketing authorization application in amyotrophic lateral sclerosis (ALS).

The timetable extension was requested by AB Science in order to address a question from the CHMP that arose following implementation of a guidance [1], updated on July 28, 2023 [2], from the EMA. This guidance requested all marketing authorisation holders to review their manufacturing processes for all products containing chemically synthesised or biological active substances to identify and, if necessary, mitigate the risk of presence of nitrosamine impurities.

Because performing this activity was not compatible with the conventional 30 days stop-clock, AB Science requested an extension of this stop-clock in order to complete a risk evaluation of the manufacturing process in terms of risk of formation of nitrosamines in active substance and finished product.

An extension of clock-stop is not automatic. A request for extension together with a corresponding scientific justification must be submitted by the applicant and needs to be discussed in a CHMP plenary session. AB Science's request was accepted during the September 11-14, 2023 CHMP session.

Based on this updated timetable, the CHMP decision on masitinib marketing authorization in ALS is expected during the first quarter of 2024.

Based on the current stage of investigations, AB Science is confident that the current manufacturing process of masitinib complies with this new EMA guidance.

References

[1] EMA/369136/2020: Nitrosamines EMEA-H-A5(3)-1490 - Assessment report.

https://www.ema.europa.eu/en/documents/referral/nitrosamines-emea-h-a53-1490-assessment-report_en.pdf

[2] EMA/409815/2020 Rev.17: Questions and answers for marketing authorization holders/applicants on the CHMP Opinion for the Article 5(3) of Regulation (EC) No 726/2004 referral on nitrosamine impurities in human medicinal products. https://www.ema.europa.eu/en/documents/referral/nitrosamines-emea-h-a53-1490-questions-answers-marketing-authorisation-holders/applicants-chmp-opinion-article-53-regulation-ec-no-726/2004-referral-nitrosamine-impurities-human-medicinal-products_en.pdf

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).

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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