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AB SCIENCE ANNOUNCES AN UPDATE IN THE MARKETING AUTHORIZATION APPLICATION OF MASITINIB IN AMYOTROPHIC LATERAL SCLEROSIS AT THE EUROPEAN MEDICINES AGENCY

A DECISION FROM THE EUROPEAN MEDICINES AGENCY IS EXPECTED DURING THE SECOND QUARTER OF 2024

Paris, 26 January, 2024, 6pm CET

AB Science SA (Euronext – FR0010557264 – AB) announced that the Committee for Medicinal Products for Human Use (CHMP) has proposed that AB Science submit a written response to the List of Outstanding Issues at D195 of the procedure, instead of addressing these issues through the Oral Explanation.

At D195 of the procedure, certain major objections remained, and an Oral Explanation was scheduled on January 24, 2024 to address these objections.

This week, before the date planned date of the Oral Explanation, the CHMP has proposed that AB Science addresses these objections in writing instead of the Oral Explanation.

AB Science has accepted this proposal, which is unusual at this stage of the procedure, as it offers AB Science the possibility of giving more detailed responses than what would be possible during an Oral Explanation, and provides CHMP with more time to evaluate the responses. A new Oral Explanation is not mandatory and will be scheduled only if major objections remain after the review of the written responses.

AB Science now expects an opinion from the CHMP in the second quarter of 2024.