

## SUMMARY OF THE WEBCAST HELD ON MAY 30, 2024, PROVIDING AN UPDATE ON THE APPLICATION FOR CONDITIONAL MARKETING AUTHORISATION OF MASITINIB IN THE TREATMENT OF AMYOTROPHIC LATERAL SCLEROSIS

Paris, May 31, 2024, 4.30pm CET

**AB** Science SA (Euronext - FR0010557264 - AB) is providing a summary of the live webcast held on May 30, 2024, giving an update on the application for conditional marketing authorization of masitinib in the treatment of amyotrophic lateral sclerosis (ALS).

The webcast presentation is available on the company's website, in the section « Press Releases »: <u>https://www.ab-science.com/news-and-media/press-releases/</u>

The presentation covered three topics:

- Conditional approval of masitinib in ALS with the European Medicines Agency (EMA)
- Conditional approval of masitinib in ALS with Health Canada
- Available preclinical and clinical data in the context of a full approval

Regarding the conditional approval of masitinib in ALS with EMA, AB Science presented the CHMP trend vote position, concluding that the safety of masitinib is deemed acceptable but outstanding issues remain preventing a favorable benefit assessment. These issues and main justifications presented by AB Science are detailed in the presentation. The EMA decision will be made public during the next CHMP meeting to be held on June 24-27, 2024.

As a next step, AB Science indicated that it has the option to request a re-examination, and that it would liaise with the EMA to define the appropriate pathway to registration. In case of re-examination, a new Rapporteur and new Co-Rapporteur are appointed to assess the dossier, and a Scientific Advisory Group) can be appointed to provide recommendations on key points. Such key points could include: Application of EMA guideline on the Good Clinical Practices (GCP), application of EMA guideline on subgroup, application of the two recommendations for handling of missing data, and whether excluding Fast progressors from primary analysis is justified.

Regarding the conditional approval of masitinib in ALS with Health Canada, AB Science presented the main clinical objections raised by Health Canada, which were slightly different from the ones raised by EMA.

Finally, AB Science clarified that a distinction was to be made between the conditional marketing authorization that requires very compelling evidence from a single study, and the available preclinical and clinical data from masitinib program, that are robust and will support full approval, provided a confirmatory study is positive.

- Masitinib has a validated mechanism of action, targeting the innate immune system, via modulation
  of mast cells and microglia. Masitinib exerts a protective effect on the central nervous system and on
  the peripheral nervous system. In addition, Masitinib has demonstrated its ability to lower blood levels
  of neurofilament light (NfL) in a neurodegenerative disease model (EAE model).
- Study AB10015 is a 48-week study, which is stronger evidence than a 24-week study, and is same time point as the confirmatory study. In addition, study AB10015 demonstrated a significant treatment effect in the primary analysis population.
- Data are exceptionally strong in the population close to the confirmatory study and that could be the claim, with a significant benefit on functional score, a significant benefit on quality of life, and a significant benefit of plus 12 months on long-term overall survival.

AB Science has asked to Euronext Paris to resume listing of its shares from the opening of trading on Monday June 03, 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: <u>www.ab-science.com</u>.

## 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.

For additional information, please contact:

## **AB** Science

Financial Communication & Media Relations investors@ab-science.com