PRESS RELEASE

AB SCIENCE ANNOUNCES NEW PUBLICATION ON MEDRXIV HIGHLIGHTING CLINICAL BENEFIT WITH MASITINIB IN AMYOTROPHIC LATERAL SCLEROSIS PATIENTS PRIOR ANY COMPLETE LOSS OF FUNCTION

- **Significant improvement in functional decline measured by the ALSFRS-R score, with a 4.04-point difference favoring masitinib over placebo (p=0.0065)**
- **Significant benefit on CAFS (relative benefit +20.2%, p=0.0290)**
- **Median progression-free survival (PFS) extended by 9 months (p=0.0057)**
- **Median overall survival (OS) increased by 12 months (p=0.0192)**

THESE RESULTS INFORMED THE DESIGN OF CONFIRMATORY STUDY AB23005, TARGETING PATIENTS PRIOR ANY COMPLETE LOSS OF FUNCTION TO OPTIMIZE THE BENEFIT-RISK BALANCE AND ENHANCE THE LIKELIHOOD OF STUDY SUCCESS

Paris, December 11, 2025, 6.30pm CET

AB Science SA (Euronext - FR0010557264 - AB) today announced the publication of a new article on the preprint platform MedRxiv, presenting a post-hoc subgroup analysis of the phase 2b/3 AB10015 study evaluating masitinib in patients with amyotrophic lateral sclerosis (ALS). This article is entitled 'Efficacy and safety of masitinib in amyotrophic lateral sclerosis patients prior to loss of functionality: a subgroup analysis optimizing the benefit-risk profile of masitinib' and is freely accessible online from the medRxiv site [1].

Albert Ludolph, MD, lead author and Senior Professor of Neurology at the University of Ulm, stated: *"Our findings highlight the importance of early intervention in ALS with masitinib, demonstrating that treatment prior to any complete loss of function can improve patient response. This subgroup analysis not only clarifies the drug's benefit-risk profile but also informs the design of future confirmatory trials, such as the approved AB23005 study."*

Professor Olivier Hermine, MD, President of the Scientific Committee of AB Science and co-author of this article commented: *"This analysis marks a significant step forward in the clinical development of masitinib for ALS, reinforcing its potential to slow disease progression and improve survival when administered early in the disease course, that is, in patients who have not yet experienced a complete loss of functionality on any item of the ALSFRS-R scale. Importantly, this patient enrichment strategy is entirely consistent with the established mechanism of action of masitinib and the therapeutic goal of preserving neuromuscular function rather than repairing existing neurological damage."*

The analysis focused on patients prior to any complete loss of functionality, a subgroup identified to optimize the benefit-risk profile of masitinib treatment, which comprised approximately 85% of the AB10015 primary analysis population. The key findings of the analysis are as follows:

- A significant improvement in functional decline was measured by the ALSFRS-R score, with a 4.04-point difference favoring masitinib over placebo (p=0.0065), surpassing the 3.39-point difference observed in the AB10015 trial population.
- A significant benefit in CAFS with a relative change versus placebo of +20.2% (p=0.029), above the +13.8% relative benefit observed in the AB10015 trial population. CAFS is the preferred endpoint for the FDA.

- The median progression-free survival (PFS) was extended by 9 months (p=0.0057), and the median overall survival (OS) increased by 12 months (p=0.0192) compared to the placebo, and both improvements were more pronounced than those in the primary analysis.
- Safety outcomes improved in this subgroup, with a reduction in serious adverse events from 27.6% to 22.6% in masitinib-treated patients.
- This subgroup, defined by patients with a score of at least 1 on all ALSFRS-R items at baseline, represents a clinically relevant population easily identifiable in practice and aligns with masitinib's mechanism of action, targeting neuroinflammation through mast cell inhibition and microglia modulation before irreversible functional loss.

Masitinib Study AB23005 in ALS

Study AB23005 (NCT07174492) is a prospective, multicenter, randomized, double-blind, placebo-controlled, two-arm study in patients with amyotrophic lateral sclerosis (ALS) to confirm the efficacy and safety of masitinib (at a dose of 4.5 mg/kg/day in combination with riluzole) as compared against riluzole in combination with placebo after 48 weeks of treatment. The study will include 408 patients (randomized 1:1) with ALS, normal disease progression (i.e., functional decline of less than 1.1 points per month), and no total loss of function (i.e., a score of at least 1 on each of the 12 items of the ALSFRS-R score). US patients receiving edaravone will also be eligible to participate in the study, with the use of this drug being a stratification factor. This design was validated through discussions with European health authorities.

AB Science has received approval from several European countries to initiate the confirmatory phase 3 study of masitinib in ALS. This authorization followed the EMA's validation of the harmonized protocol, approved at the end of Step 1 of the CTIS procedure, and followed the authorization from the FDA. Consequently, AB Science can now initiate this registration study in Europe and the United States [2].

References

[1] Albert C Ludolph, Jesus S Mora, Patrick Vermersch, Alain Moussy, Colin D Mansfield, Olivier Hermine. Efficacy and safety of masitinib in amyotrophic lateral sclerosis patients prior to loss of functionality: A subgroup analysis optimizing the benefit-risk profile of masitinib. medRxiv 2025.12.08.25341479; doi: https://doi.org/10.64898/2025.12.08.25341479

[2] AB Science press release 24/07/2025 – https://www.ab-science.com/category/news/2025/

About MedRxiv

MedRxiv (pronounced "med-archive") is a free online archive and distribution service for unpublished preprints in the life sciences. Launched to accelerate communication and collaboration across the medical community, the platform provides early access to important studies prior to peer review, helping researchers, clinicians, and public health leaders stay informed about emerging evidence.

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.

For additional information, please contact:

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