



A NEW PUBLICATION IN THE MEDICAL JOURNAL *MUSCLE & NERVE* VALIDATES THE USE OF THE RATE OF DECLINE OF ALSFRS-R SCORE (Δ FS) FOR THE DESIGN OF CLINICAL STUDIES AND THE TREATMENT CHOICE FOR AMYOTROPHIC LATERAL SCLEROSIS (ALS) PATIENTS

THIS PUBLICATION VALIDATES THE CLINICAL TRIAL DESIGN OF MASITINIB PHASE 2/3 STUDY AB10015 AND CONFIRMATORY STUDY IN ALS

Paris, May 07, 2024, 6pm CET

AB Science SA (Euronext - FR0010557264 - AB) today announced the publication of an article in *Muscle & Nerve*, a peer-reviewed medical journal covering neuromuscular medicine. This article, published as part of the journal's Issues & Opinions section, discusses the merits of using the clinical parameter of delta FS (Δ FS), the slope or rate of ALSFRS-R decline over time, as a relevant tool for innovative amyotrophic lateral sclerosis (ALS) study design. The article, entitled '*Categorization of the amyotrophic lateral sclerosis population via the clinical determinant of post-onset Δ FS for study design and medical practice*', is accessible online from the *Muscle & Nerve* website (<https://onlinelibrary.wiley.com/doi/epdf/10.1002/mus.28101>) [1].

Authored by experts in the field of ALS, the article concludes that post-onset Δ FS serves not only as a critical stratification factor and basis for patient enrichment, but also as a tool to explore differences in treatment response across the overall population for identification of preferential responder subgroups. Furthermore, because post-onset Δ FS is derived from information routinely collected as part of standard patient care and monitoring, it provides a suitable patient selection tool for treating physicians. Post-onset Δ FS (or early Δ FS), is the rate of decline of the total ALSFRS-R score (i.e., the slope of ALSFRS-R over time), calculated from the date of initial symptom onset.

These observations are highly relevant to the masitinib development program in ALS because study AB10015 was based precisely on this design strategy [2].

Professor Albert Ludolph, MD, PhD, Chairman of the Department of Neurology at the University Hospital and Medical Faculty of Ulm and senior author of this article commented: "*In this article we discuss the merits of post-onset Δ FS as a tool for innovative ALS study design. Δ FS is a clinically relevant, independent predictor of survival, capable of distinguishing patient subgroups that have a different course of disease progression. Categorization of the ALS population via post-onset Δ FS is therefore an important study design consideration that may facilitate optimization of drug effectiveness and patient management, and as such is recommended for inclusion in the design of clinical trials.*"

Professor Olivier Hermine, MD, PhD, President of the Scientific Committee of AB Science and member of the Académie des Sciences in France said: "*Although this article is not specifically directed towards the masitinib study AB10015 in ALS, it describes very well the design philosophy behind that study and as such is a strong validation of this approach. Importantly, it shows that there is consensus among these key opinion leaders that post-onset Δ FS is a simple-to-use instrument for patient selection, with no obvious barriers regarding its application in clinical practice.*"

➤ Key points from this article include:

- Rate of ALSFRS-R decline (Δ FS) is a clinically relevant, independent predictor of survival, capable of distinguishing patient subgroups that have a different course of disease progression.
- Post-onset Δ FS is an independent prognostic factor that has relevance for patient selection, irrespective of changes to Δ FS categorization at later stages of the disease course.
- Post-onset Δ FS is a simple-to-use instrument for patient selection, the components of which are measured as part of routine clinical practice.
- The use of post-onset Δ FS patient categorization allows for innovative ALS trial design that may facilitate optimization of drug effectiveness and patient management.
- Overall, there are no insurmountable barriers regarding the application of post-onset Δ FS in clinical practice, making it very attractive enrichment tool that is, can and should be regularly incorporated into ALS trial design.

[1] Ludolph AC, Corcia P, Desnuelle C, Heiman-Patterson T, Mora JS, Mansfield CD, Couratier P. Categorization of the amyotrophic lateral sclerosis population via the clinical determinant of post-onset Δ FS for study design and medical practice. *Muscle Nerve*. Published online May 05, 2024. doi:10.1002/mus.28101 (available from <https://onlinelibrary.wiley.com/doi/epdf/10.1002/mus.28101>)

[2] Mora JS, Genge A, Chio A, et al. Masitinib as an add-on therapy to riluzole in patients with amyotrophic lateral sclerosis: a randomized clinical trial. *Amyotroph Lateral Scler Frontotemporal Degener*. 2020;21(1-2):5-14. doi:10.1080/21678421.2019.1632346

About Muscle & Nerve

Muscle & Nerve is devoted to publishing new clinical and research studies on the most important findings on neuromuscular disorders and treatment options from a range of medical fields. The 2022 Journal Impact Factor (Clarivate) of Muscle and Nerve is 3.4.

About masitinib

Masitinib is a orally administered tyrosine kinase inhibitor that targets mast cells and macrophages, important cells for immunity, through inhibiting a limited number of kinases. Based on its unique mechanism of action, masitinib can be developed in a large number of conditions in oncology, in inflammatory diseases, and in certain diseases of the central nervous system. In oncology due to its immunotherapy effect, masitinib can have an effect on survival, alone or in combination with chemotherapy. Through its activity on mast cells and microglia and consequently the inhibition of the activation of the inflammatory process, masitinib can have an effect on the symptoms associated with some inflammatory and central nervous system diseases and the degeneration of these diseases.

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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