



## PRESS RELEASE

**AB SCIENCE HAS BEEN AUTHORIZED BY THE SWEDISH MEDICAL PRODUCTS AGENCY TO INITIATE CONFIRMATORY PHASE III TRIAL OF MASITINIB IN PROGRESSIVE FORMS OF MULTIPLE SCLEROSIS**

**SWEDEN IS THE SECOND EUROPEAN COUNTRY TO AUTHORIZE THE STUDY AFTER THE APPROVAL RECEIVED BY THE FRENCH MEDICINE AGENCY**

*Paris, 02 February, 2022, 6pm CET*

**AB Science SA** (Euronext - FR0010557264 - AB) today announces that it has been authorized by the Swedish Medical Products Agency, to initiate a Phase III study (AB20009) evaluating masitinib in patients with Primary Progressive Multiple Sclerosis (PPMS) or non-active Secondary Progressive Multiple Sclerosis (nSPMS).

Study AB20009 is titled *'A 96-Week, Prospective, Multicenter, Randomised, Double-Blind, Placebo-Controlled, Phase 3 Study to Compare Efficacy and Safety of Masitinib Dose Titration to 4.5 mg/kg/day versus Placebo in the Treatment of Patients with Primary Progressive or Secondary Progressive Multiple Sclerosis Without Relapse'*.

Professor Olivier Hermine, President of the Scientific Committee of AB Science and member of the Académie des Sciences in France said, *"This latest approval, coming just a few weeks after receiving similar authorization from the French Medicine Agency, represents a key step not only for the clinical program of masitinib in progressive forms of multiple sclerosis, but also for the overall masitinib pipeline in neurology. To date, masitinib has demonstrated positive Phase 2B/3 results in three neurodegenerative disorders, namely, Alzheimer's disease [1], amyotrophic lateral sclerosis (ALS) [2,3], and progressive forms of multiple sclerosis [4]. Success in these three diverse indications clearly demonstrates that masitinib's innovative targeting of the innate immune system is a valid strategy. We are committed to continue masitinib's clinical development program in each of these highly challenging neurological disorders, with an ultimate objective to improve patients' lives."*

Study AB20009 has also been approved by the French Medicine Agency, ANSM.

The study will enroll 800 patients from numerous study centers with Expanded Disability Status Scale (EDSS) score between 3.0 to 6.0 and absence of T1 Gadolinium-enhancing brain lesions as measured by magnetic resonance imaging (MRI). The primary objective of the study will be to evaluate the effect of masitinib on time to confirmed disability progression, with progression defined as 1-point worsening when EDSS baseline score  $\leq 5.5$ , or 0.5 if baseline score  $> 5.5$  from randomization to week 96.

This confirmatory study follows successful completion of a first Phase 2B/3 study (AB07002) in primary progressive (PPMS) and non-active secondary progressive (nSPMS) multiple sclerosis. Results from that study were presented during the 8<sup>th</sup> Joint Americas Committee for Treatment and Research in Multiple Sclerosis (ACTRIMS) – European Committee for Treatment and Research in Multiple Sclerosis (ECTRIMS) Meeting (MSVirtual2020). The study met its primary analysis endpoint, demonstrating a statistically significant reduction in cumulative change on EDSS with masitinib 4.5 mg/kg/day ( $p=0.0256$ ). This treatment-effect was consistent for PPMS and nSPMS. In addition, masitinib significantly reduced the risk of first disability progression by 42% and the risk of confirmed (3 months) disability progression by 37%. Masitinib also

significantly reduced the risk of reaching an EDSS score of 7.0, corresponding to disability severe enough that the patient is restricted to a wheelchair (p=0.0093).

## References

[1] Dubois, B., Hermine, O. and (2021), Masitinib in mild to moderate Alzheimer's disease: Results from study AB09004. *Alzheimer's Dement.*, 17: e049866. <https://doi.org/10.1002/alz.049866>

[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

[3] Mora JS, Bradley WG, Chaverri D, et al. Long-term survival analysis of masitinib in amyotrophic lateral sclerosis. *Ther Adv Neurol Disord.* 2021;14:17562864211030365. Published 2021 Jul 19. doi:10.1177/17562864211030365

[4] Vermersch P, Hermine O. Masitinib in primary progressive (PPMS) and non-active secondary progressive (nSPMS) multiple sclerosis: results from phase 3 study AB07002. *MSVirtual2020; virtual*; Sept 11–13, 2020 (abstr FC04.01). <https://msvirtual2020.org/wp-content/uploads/2020/09/FC04.01.pdf>

## A strong medical need for the progressive forms of multiple sclerosis

Multiple sclerosis is an autoimmune disease of the central nervous system that affects more than 100,000 people in France and for which no definitive treatment exists to date. It is characterized by a progressive degradation of the nerve cells of the central nervous system by the patient's immune system and comes in two main forms.

The relapsing-remitting form characterized by relapses of the disease. During these relapses, patients experience the onset of new symptoms or the worsening of symptoms already present. These flare-ups are usually followed by recovery periods of varying length, after which some symptoms may persist. The relapsing-remitting forms of multiple sclerosis are mostly associated with dysfunctions of adaptive immunity (B cells and T cells).

The progressive form, characterized by a constant and regular worsening of the symptoms of the disease, without a distinct relapse or period of recovery. The rate of onset of severe, disabling, and irreversible disability is much higher in the progressive forms of the disease than in the relapsing remitting forms. In progressive multiple sclerosis, innate immune cells such as macrophages, microglia or mast cells have been shown to probably play a major role.

## 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](http://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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