



AB SCIENCE TO PRESENT ON ITS AMYOTROPHIC LATERAL SCLEROSIS (ALS) DEVELOPMENT PROGRAM AT THE 2022 ALS DRUG DEVELOPMENT SUMMIT

Paris, 07 February, 2022, 6pm CET

AB Science SA (Euronext - FR0010557264 - AB) today announced that Professor Olivier Hermine, President of the Scientific Committee of AB Science, will deliver a presentation on the amyotrophic lateral sclerosis (ALS) masitinib development program to an audience of key opinion leaders and decision-makers in the field of ALS research and healthcare policy, at the up-coming *ALS Drug Development Summit* in Boston, USA (May 24-26, 2022).

The title of this presentation is ‘Exploring Mastocytosis & Kinases as the Basis of the History of Masitinib in ALS Mechanism of Action & Reviewing Clinical Results’.

Professor Olivier Hermine said, *“This invited platform presentation will be an opportunity to connect with key stakeholders and opinion leaders from the ALS research and healthcare communities, to discuss the past and future development of masitinib in ALS. New drugs are still urgently needed for ALS, especially in light of a recent article from the German Motor Neuron Disease Network, published in the journal JAMA Neurology, which reported on the difficulty in reproducing ALS clinical trial results in a real-world clinical setting [1].”*

Additional information on the ALS Drug Development Summit can be found at the meeting website: <https://www.als-drug-development.com/>.

As a reminder, the development program of masitinib in ALS comprises a 48-week clinical trial (AB10015), including long-term survival follow-up analysis, and an on-going confirmatory phase 3 trial (AB19001), also with a 48-week endpoint. The development of masitinib in ALS is also supported by a well-demonstrated mechanism of action using a relevant model.

Study AB10015 previously showed that masitinib (4.5 mg/kg/day) as an add-on to standard riluzole, significantly slowed functional decline at week 48 relative to those treated with riluzole alone [2]. Furthermore, long-term follow-up analysis showed a significantly prolonged survival of 25 months in favor of masitinib, provided that treatment was initiated at an early stage of disease [3].

Regarding study design, the aforementioned German Motor Neuron Disease Network article [1] also concluded that evaluating effectiveness using a too short-term (i.e., 24 weeks) ALSFRS-R score decrease, may have limitations. This, therefore, is a differentiating feature from study AB10015, which was based on a 48-week treatment time point.

About masitinib in neurodegenerative disorders

To date, masitinib has demonstrated positive Phase 2B/3 results in three neurodegenerative disorders, namely, amyotrophic lateral sclerosis (ALS) [2,3], Alzheimer’s disease [4], and progressive forms of multiple sclerosis [5]. Success in these three diverse indications clearly demonstrates that targeting the innate immune system including macrophage/microglia and mast cells, through inhibition of tyrosine kinases as masitinib does, is a valid strategy.

About Study AB19001

Study AB19001 has been authorized in more than 15 countries in Europe, USA, and other regions and is actively enrolling patients.

Study AB19001 is an international, multicenter, randomized, double-blind, placebo-controlled, 3-parallel group, Phase 3 study to compare the efficacy and safety of masitinib in combination with riluzole versus placebo in combination with riluzole for the treatment of people suffering from ALS.

The study is intended to confirm the previously published results from the first Phase 2b/3 study (AB10015), which demonstrated that masitinib at 4.5 mg/kg/day in combination with riluzole significantly slowed functional decline by 27% compared with riluzole alone at week 48, as measured by change in ALSFRS-R (Amyotrophic Lateral Sclerosis Functional Rating Scale-revised).

Study AB19001 recruitment targets people with ALS that have mild or moderate (non-severe) impairment of functionality at baseline. This is closely aligned with the patient population that showed the greatest survival benefit with masitinib in the long-term survival analysis. The primary endpoint of study AB19001 is absolute change from baseline in functional score as assessed by ALSFRS-R after 48 weeks of treatment.

References

- [1] Witzel S, Maier A, Steinbach R, et al. [published online ahead of print, 2022 Jan 10]. *JAMA Neurol.* 2022;e214893. doi:10.1001/jamaneurol.2021.4893
- [2] Mora JS; Bradley WG; Chaverri D, et al. *Ther Adv Neurol Disord* 2021, Vol. 14: 1–16
- [3] Mora JS, Genge A, Chio A, et al. *Amyotroph Lateral Scler Frontotemporal Degener.* 2020;21(1-2):5-14.
- [4] Dubois B, Hermine O, et al. (2021). *Alzheimer's Dement.*, 17: e049866. <https://doi.org/10.1002/alz.049866>
- [5] Vermersch P, Hermine O. *MSVirtual2020; virtual; Sept 11–13, 2020 (abstr FC04.01).* <https://msvirtual2020.org/wp-content/uploads/2020/09/FC04.01.pdf>

About amyotrophic lateral sclerosis

Amyotrophic lateral sclerosis (ALS) is a fatal motor neuron disorder that is characterized by progressive loss of the upper and lower motor neurons at the spinal or bulbar level. The disease belongs to a group of disorders known as motor neuron diseases, which are characterized by the gradual degeneration and death of motor neurons. In ALS, both the upper motor neurons and the lower motor neurons degenerate or die, and stop sending messages to muscles.

The prevalence of ALS in western countries is fairly uniform at 6 per 100,000 persons, corresponding to around 30,000 cases in Europe and 20,000 in the USA.

The first drug treatment for ALS, riluzole (Rilutek), was approved in 1995. In Europe, there has been no new treatment approved since riluzole.

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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