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AB Science announces positive top-line Phase 2B/3 results for oral masitinib in progressive forms of multiple sclerosis

Masitinib significantly delays disability progression on EDSS in patients with primary progressive (PPMS) and non-active secondary progressive (nSPMS) multiple sclerosis

AB Science SA (Euronext - FR0010557264 - AB) today announced that the Phase 2B/3 study (AB07002) evaluating oral masitinib in primary progressive (PPMS) and non-active secondary progressive (nSPMS) multiple sclerosis met its primary endpoint (p=0.0256) with masitinib dose of 4.5 mg/kg/day. This treatment-effect was numerically maintained for subpopulations of PPMS and nSPMS.

The study enrolled 301 patients in the 4.5 mg/kg/day treatment arm (200 treated with masitinib and 101 treated with placebo). The pre-specified primary endpoint was absolute change from baseline on Expanded Disability Status Scale (EDSS) considering all measurements from week-12 to week-96. Results on the primary endpoint were supported by pre-specified statistically significant sensitivity analysis based on the ordinal EDSS model. Additionally, masitinib significantly delayed disease progression as measured by the time to reach an EDSS score of 7.0 (corresponding to disability severe enough that the patient is restricted to a wheelchair).

Efficacy analysis was performed in the modified intent-to-treat (mITT) population, which included all randomized patients who took at least one dose of study treatment (masitinib/placebo).

The proportion of patients experiencing at least one adverse event was 95.0% for masitinib (4.5 mg/kg/day) versus 87.1% for placebo. Safety was consistent with the known tolerability profile for masitinib.

The study also enrolled 310 patients in a 6.0 mg/kg/day (titration starting at 4.5 mg/kg/day) treatment arm (203 treated with masitinib and 107 treated with placebo). There was no significant improvement with respect to placebo at this higher dose of masitinib.

Primary progressive MS (PPMS) is characterized by steadily worsening function from the onset of symptoms, often without early relapses or remissions. PPMS affects about 15% of people diagnosed with MS. Non-active secondary progressive MS (nSPMS) is a stage of MS that follows relapsing-remitting multiple sclerosis and that is characterized with an EDSS score progression ≥ 1 point without any relapse in the last 2 years. nSPMS affects about 30-35% of people with MS.

Patrick Vermersch, Professor of Neurology at Lille University in France and coordinating investigator of study AB07002 said, "*People with primary progressive (PPMS) and non-active secondary progressive (nSPMS) forms of multiple sclerosis account for half of all MS patients. While numerous treatments based on targeting of B-cells and T-cells of the adaptive immune system are available for patients with relapsing forms of MS, these strategies have failed or had inconclusive results in PPMS and nSPMS. Consequently, there remains a very high medical need for people with* PPMS and nSPMS*. Masitinib does not target the adaptive immune system and the results from this study represent a scientific breakthrough because this is the first time that the novel strategy of targeting the innate immune system via mast cells and microglia has been able to significantly slow progression of clinical disability in progressive forms of MS. These data are extremely encouraging and may provide new hope for progressive MS patients*".

Prof. Olivier Hermine (President of the Scientific Committee of AB Science and member of the Académie des Sciences in France) said, "*This positive result in progressive MS is an important new finding that further*

validates the mechanism of action of masitinib in neurodegenerative diseases [1]. Indeed, this is the second piece of supportive evidence delivered by the masitinib clinical program. The first one was the positive Phase 2B/3 study with masitinib in amyotrophic lateral sclerosis (ALS) [2]. The second one is this new positive Phase 2B/3 study in progressive forms of MS, which share similar characteristics with other neurodegenerative diseases. The two studies taken together clearly demonstrate that targeting the innate immune system via macrophage/microglia and mast cells, as masitinib does, is one of the right strategies to treat neurodegenerative disorders. This is a true innovation that justifies the long-term efforts from AB Science to develop masitinib in ALS, progressive forms of MS and Alzheimer's disease."

A new patent was filed based on results from study AB07002.

The company will consult with the Health Authorities to discuss the appropriate pathway forward for masitinib in the treatment of progressive forms of multiple sclerosis.

AB Science plans to present detailed study results at an upcoming medical meeting. The top-line results will be further discussed in the coming weeks during a live webcast on masitinib in progressive forms of multiple sclerosis with Key Opinion Leaders.

[1]: Stys PK and Tsutsui S. F1000Res. 2019 Dec 13;8. pii: F1000 Faculty Rev-2100.
[2]: Mora JS et al. Amyotroph Lateral Scler Frontotemporal Degener. 2019 Jul 7:1-10.

Phase 3 study in progressive PPMS and nSPMS

The Phase 2B/3 trial (AB07002) was a prospective, multicenter, randomized (2:1), double-blind, placebo-controlled, 2-parallel groups study evaluating oral masitinib as a treatment for progressive multiple sclerosis (MS) tested at 4.5 mg/kg/day and 6 mg/kg/day (titration starting at 4.5 mg/kg/day). Eligible patients aged 18-75 years, with baseline Expanded Disability Status Scale (EDSS) 2.0–6.0, regardless of time-from-onset, and diagnosed with primary progressive (PPMS) or non-active secondary progressive (nSPMS) MS, were treated for 96 weeks.
The pre-specified primary endpoint was the overall EDSS (Expanded Disability Status Scale) change from baseline using repeated measures (GEE model, timeframe W12–W96). The pre-specified sensitivity analysis was based on the ordinal EDSS model (GEE model, timeframe W12–W96).
The primary endpoint was overall EDSS change from baseline using repeated measures (GEE model, timeframe W12–W96).

About masitinib
Masitinib is a new 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, and inflammatory 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 filed by AB Science with the Autorité des Marchés Financiers (AMF), including those listed in the Chapter 4 "Risk Factors" of AB Science reference document filed with the AMF on November 22, 2016, under the number R. 16-078. 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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