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The masitinib phase 3 study in Alzheimer's disease has completed patient recruitment

Final results will be available in 2019

AB Science SA (NYSE Euronext – FR0010557264 – AB), a pharmaceutical company specialized in the research, development and marketing of protein kinase inhibitors (PKIs), announces today that the masitinib phase 3 study in Alzheimer's disease has completed patient recruitment.

Phase 2/3 study of masitinib in Alzheimer's disease

The phase 3 study (AB09004) is a double-blind, randomized, placebo-controlled trial designed to assess the safety and efficacy of masitinib in patients with confirmed mild to moderate Alzheimer's disease. The treatment period is 24 weeks and masitinib is given as add-on therapy to cholinesterase inhibitor (donepezil, rivastigmine or galantamine and/or memantine). The main efficacy endpoints are the change in two commonly used clinical assessments: the effect on ADCS-ADL, which measures self-care and activities of daily living, and the effect on ADAS-Cog, which measures the effect on cognition and memory.

Study recruitment was completed with 721 enrolled patients.

The Independent Data Safety Monitoring Committee (IDMC) has, on each occasion, recommended the continuation of this phase 3 study based on the analysis of the safety data, and once based on the result of an efficacy futility test.

Final analysis is expected in 2019.

The next step for this study is a pre-planned interim analysis, which is expected in the coming months.

Scientific rationale for the evaluation of masitinib in Alzheimer's disease

The therapeutic benefit of masitinib in Alzheimer's disease is most likely exerted through multiple mechanisms of action:

- Masitinib potently inhibits mast cell, cells that play an important role in neuroinflammation and regulation of the blood-brain-barrier (BBB) permeability [1].
- Masitinib also targets the FYN kinase, which is involved in A β signaling and Tau phosphorylation [2].
- Masitinib also targets CSF1R kinase, which is involved in the regulation of the microglial cell neuroinflammatory response [1,3].

A proof of concept study has been conducted. The results have been published in [Alzheimers Res Ther.](#) 2011 Apr 19;3(2):16. doi: 10.1186/alzrt75.

Targeted population

Estimations in the prevalence of Alzheimer's disease varies. Yet Alzheimer's disease remains a major health problem with between 5 and 10 million people affected in the USA and Europe. Alzheimer's disease is the most common type of dementia among western countries, corresponding to about 60% of cases. Alzheimer's disease is already the sixth leading cause of all deaths in USA and the fifth cause among Americans aged more

than 65 years.^{4,5,6} Worldwide it is thought that there are more than 15 million people affected by Alzheimer's disease.⁶

References

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- [4] Rizzi L, et al. Biomed Res Int. 2014;2014:908915. doi: 10.1155/2014/908915.
- [5] Launer LJ, et al. Neurology. 1999 Jan 1;52(1):78-84. doi:10.1155/2014/908915.
- [6] Weili Xu et al. Epidemiology of Alzheimer's Disease, Understanding Alzheimer's Disease. 2013.doi: 10.5772/54398.

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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