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AB Science announces positive top-line Phase 3 results for oral masitinib in severe asthma

Masitinib statistically significantly reduced the rate of severe asthma exacerbations compared to placebo

AB Science SA (Euronext - FR0010557264 - AB) today announced that the Phase 3 study (AB07105) evaluating oral masitinib in severe asthma uncontrolled by oral corticosteroids met its primary endpoint (p=0.0103). The pre-specified primary endpoint of the protocol was the severe asthma exacerbation rate. The results on the primary endpoint remained statistically significant across all pre-specified sensitivity analyses, indicating that the results are consistent and robust.

In particular, the treatment effect was significant in two pre-specified populations: 1) with severe asthma that were not well controlled with oral corticosteroids at a minimal daily dose greater than 5 mg prednisone; and 2) with severe asthma with elevated eosinophil levels ($\geq$ 0.15 K/uL) and not well controlled with oral corticosteroids at a minimal daily dose greater than 5 mg prednisone.

The occurrence of adverse events (AEs) and serious adverse events (SAEs) was comparable between masitinib and placebo. AEs and SAEs occurred respectively in 83.4% and 17.7% of patients receiving masitinib, *versus* 82.0% and 16.5% of patients receiving placebo.

More detailed results will be presented at an upcoming medical meeting.

"*We are very pleased with these positive results which suggest that masitinib could be a new oral treatment option in this difficult to treat population asthma population, including for severe eosinophilic asthma*", said Lavinia Davidescu, MD, PhD, principal coordinating investigator of the study.

Asthma uncontrolled by oral corticosteroids represents the most severe form of asthma (GINA step V patients that are uncontrolled) and represents a high unmet medical need. The quality of life of these patients is severely impacted, with a major reduction in lung function, restrictions on activities of daily living, work absenteeism, night-time awakening several times a week, frequent exacerbations and greater risk of life-threatening asthma exacerbations.

"*This is the first positive large scale study in severe asthma utilizing a tyrosine kinase inhibitor, offering an alternative to monoclonal antibodies which are administered intravenously. It also supports the idea that mast cells are an important therapeutic target in severe asthma*", said Olivier Hermine, Co-Chairman of the Scientific Committee of AB Science and member of the French Academy of Science.

"These clinical results are supported by a strong scientific rationale", added Jean-Pierre Kinet, MD, Co-Chairman of the Scientific Committee of AB Science. "*Indeed, masitinib is a potent and selective blocker of mast cells, and it is well established that mast cells play an important role in asthma, not only in immediate hypersensitivity and in the late inflammation phase but also in tissue remodeling of the airways*".

Intellectual Property for masitinib is secured in asthma until 2032. The U.S. Patent and Trademark Office has granted a patent (13/983626) relating to methods of treating severe persistent asthma with masitinib. This patent, protects the use of masitinib in the treatment of severe persistent corticosteroid-dependent asthma and severe persistent corticosteroid-resistant asthma.

The company plans to host a live webcast in the coming weeks on masitinib in severe asthma with Key Opinion Leaders.

Phase 3 studies in asthma

The Phase 3 trial (AB07015) is a prospective, multicenter, randomised, double-blind, placebo-controlled, 2-parallel groups, Phase 3 study to compare the efficacy and the safety of masitinib at 6 mg/kg/day *versus* placebo in the treatment of patients with severe persistent asthma uncontrolled by oral corticosteroids. The study enrolled 355 assessable patients. The pre specified primary endpoint of the protocol was the severe asthma exacerbation rate (i.e. the number of severe asthma exacerbations divided by the time under treatment for the overall protocol period). This overall protocol period consisted of the main protocol period (from baseline to week 36 time point) together with the extension period (after the week 36, patients could continue treatment in their original treatment arm without unblinding). This overall protocol period was well balanced between the two treatment arms.

A second Phase 3 trial (AB14001) is on-going with masitinib in asthma. It is a prospective, multicenter, randomised, double-blind, placebo-controlled, 2-parallel groups, Phase 3 study evaluating the efficacy and safety of masitinib in asthma uncontrolled by high-dose inhaled corticosteroids and with elevated eosinophil level. The primary endpoint of this study is the rate of severe asthma exacerbations over the treatment period. The planned recruitment is 350 assessable patients. The study results are expected in the first half of 2020.

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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