Paris, 20 March 2014, 7:00 pm

AB Science receives CHMP negative opinion on appeal for conditional authorization of Masitinib in second-line treatment of GIST.

AB Science intends to file for full approval in this indication with data from the on-going confirmatory phase 3 study.

AB Science SA (NYSE Euronext – FR0010557264 – AB), a pharmaceutical company specialized in research, development and marketing of protein kinase inhibitors (PKIs), announces that the Committee for Medicinal Products for Human Use (CHMP) of the European Medicine Agency (EMA) has adopted a negative opinion on the conditional marketing authorization for Masican (Masitinib mesylate) for the treatment of malignant gastrointestinal stromal tumor (GIST) resistant to first-line treatment. This decision is on the appeal filed by AB Science following a previous negative opinion adopted by the CHMP in November 2013.

The CHMP considered that the study did not provide enough evidence to be confident that the overall survival benefit was robust and that the safety profile was sufficiently characterized, and therefore considered that the benefits of masitinib did not outweigh its risks.

AB Science disagrees with the CHMP conclusion.

There is strong evidence indicating the risk-benefit balance was in fact positive since pivotal study AB07001 was an unbiased randomized trial demonstrating a statistically superior safety profile for masitinib with respect to the active comparator. Furthermore, the trial's primary analysis was successful and secondary analysis revealed a statistically significant increase of 12 months in median overall survival for the masitinib treatment-arm, a result that represents an unbiased estimate of the impact of addition of masitinib to the current standard of care in this rare and life-threatening disease.

The cornerstone of the appeal process was to explain that the observed increase in survival with no difference on the control of tumor progression was mainly due to masitinib's mechanism of action based on immune response. Regretfully according to AB Science, this new masitinib's mechanism of action has not been sufficiently investigated by the Scientific Advisory Group (SAG) and has not been sufficiently taken into account in the decision taken by the CHMP.

The CHMP, in a conservative manner, based its decision on the guideline applicable for full marketing authorization rather than on the guideline applicable for conditional marketing authorization.

AB Science considers that the CHMP opinion departs from the intention set in the European Commission Regulation to accelerate the access to new therapies presenting a positive risk-benefit balance in life-threatening diseases in order to meet unmet medical needs of patients (Commission Regulation on the conditional marketing authorization – see infra).

For clarity and transparency, the oral presentation delivered to CHMP by AB Science and detailing the case can be viewed on AB Science website, in the "News" section.

This decision does not affect the perspective to obtain marketing authorization of masitinib in this indication. AB Science intends to file for marketing authorization with data from the phase 3 confirmatory study that is currently recruiting patients in second-line treatment of GIST.

About European Commission Regulation on the conditional marketing authorization

The Commission Regulation (EC) No 507/2006 of 29 March 2006 on the conditional marketing authorization for medicinal products for human stipulates in its preamble that "In the case of certain categories of medicinal products, […], in order to meet unmet medical needs of patients and in the interests of public health, it may be necessary to grant marketing authorizations on the basis of less complete data than is normally the case and subject to specific obligations, hereinafter 'conditional marketing authorizations'. The categories concerned should be medicinal products which aim at the treatment, prevention or medical diagnosis of seriously debilitating or life-threatening diseases, […] or medicinal products designated as orphan medicinal products in accordance with Regulation." and that "Although the data upon which an opinion on a conditional marketing authorization is based may be less complete, the risk-benefit balance, as defined in Article 1(28a) of Directive 2001/83/EC should be positive. Furthermore, the benefits to public health of making the medicinal product concerned immediately available on the market should outweigh the risk inherent in the fact that additional data are still required."

About masitinib

Masitinib received orphan drug status from EMA and FDA in the treatment of GIST.

Masitinib is a new orally administered tyrosine kinase inhibitor that targets mast cells, important cells for immunity, as well as a limited number of kinases that play key roles in various cancers. Owing to its novel 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. Through its activity of inhibiting certain kinases that are essential in some oncogenic processes, masitinib may have an effect on tumor regression, alone or in combination with chemotherapy. Through its activity on the mast cell and certain kinases essential to the activation of the inflammatory cells and fibrosing tissue remodeling, masitinib can have an effect on the symptoms associated with some inflammatory and central nervous system 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 new class of targeted molecules whose action is to modify signaling pathways within cells. Through these PKIs, the Company targets diseases with high unmet medical needs (cancer, inflammatory diseases, and central nervous system diseases), in both human and veterinary medicines.

AB Science has developed a proprietary portfolio of molecules and the Company's lead compound, masitinib, has already been registered for veterinary medicine in Europe and in the USA, and is pursuing thirteen phase 3 studies in human medicine in first-line and second-line GIST, metastatic melanoma expressing JM mutation of c-Kit, multiple myeloma, metastatic colorectal cancer, metastatic prostate cancer, pancreatic cancer, mastocytosis, severe persistent asthma, rheumatoid arthritis, Alzheimer's disease, progressive forms of multiple sclerosis, and Amyotrophic Lateral Sclerosis. The company is headquartered in Paris, France, and listed on Euronext Paris (ticker: AB).

Further information is available on AB Science website: www.ab-science.com.

This document contains prospective information. No guarantee can be given as for the realization of these forecasts, which are subject to those risks described in documents deposited by the Company to the Authority of the financial markets, including trends of the economic conjuncture, the financial markets and the markets on which AB Science is present.

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AB Science – Financial Communication & Media Relations
investors@ab-science.com