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**AB Science announces that CHMP has adopted a first negative opinion for Masitinib in second-line treatment of Gastro-Intestinal Stromal Tumor (GIST)**

**AB Science will appeal this decision and continue to work with CHMP to address pending concerns to reach positive consensus for second opinion**

**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 first negative opinion for Masican (Masitinib mesylate) for the treatment of malignant gastrointestinal stromal tumour (GIST) resistant to first line treatment.

The CHMP mentions three concerns that create uncertainties which are the exploratory nature of the study making it difficult to interpret the survival benefit, the limited sample size for safety and the uncertainties on impurities in manufacturing.

The company points out that the study was not exploratory since primary analysis measuring masitinib PFS above a predefined cut was successful and secondary analysis statistically predefined as a comparison between masitinib and sunitinib was successful also on survival, leading to an extended survival of +12 months for masitinib treated patients, a very relevant clinical benefit. Safety was improved with masitinib which is also a major benefit for the patients. 1500 patients has been exposed to masitinib in the current clinical program and in GIST the pharmacokinetics being the same in second line treatment of GIST after imatinib as in first line treatment of GIST, the safety database can be extended to first line patients where masitinib is also investigated. For a rare disease this safety database seems acceptable. Additional data will be available in time to address CHMP concerns regarding certain impurities level.

AB Science will continue to work with the CHMP to respond to the pending concerns to reach positive consensus and obtain conditional approval of masitinib in GIST refractory.

Consequently AB Science will appeal the decision of the CHMP to continue the review process. A scientific advisory group that could not have been held during the first cycle of review will facilitate the assessment. This appeal should lead the CHMP to deliver a second opinion in the course of 2014.

AB Science reminds that what is at stake is the conditional approval of masitinib in GIST refractory and not the full approval. In case of immediate availability of masitinib in GIST refractory in Europe, on the basis of the presented study survival results, an estimated additional 1000 patients per year in Europe may survive as compared to the current standard of care. The law on accelerated approval should apply to the type of circumstances such as masitinib in GIST refractory.

**About masitinib**

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 ten on-going phase 3 studies in human medicine in GIST, metastatic melanoma expressing JM mutation of c-Kit, multiple myeloma, mastocytosis, severe persistent asthma, rheumatoid arthritis, Alzheimer's disease, progressive forms of multiple sclerosis, and in 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](http://www.ab-science.com).

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