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European Medicines Agency Accepts Marketing Application for Masitinib in the Treatment of Gleevec® resistant Gastro-Intestinal Stromal Tumor

AB Science SA (NYSE Euronext - FR0010557264 - AB), a pharmaceutical company specializing in the research, development and commercialization of protein kinase inhibitors (PKIs), announced that the European Medicines Agency (EMA) has accepted for review a Marketing Authorization Application (MAA) for masitinib in the treatment of patients with Gleevec®-resistant gastro-intestinal stromal tumors (GIST).

Filing for the Marketing Authorization of masitinib in GIST resistant to Gleevec® was accepted by EMA on the basis of results from a phase II study that showed masitinib to significantly improve overall survival in patients with Gleevec®-resistant GIST as compared with Sutent® (sunitinib) from Pfizer, which is currently the standard of care for second-line treatment of GIST.

In this study, 44 patients with inoperable, locally advanced or metastatic GIST and showing disease progression while treated with Gleevec® (imatinib) (400 to 800 mg/day) received either masitinib (23 patients) at 12 mg/kg/day or sunitinib (21 patients) at 50 mg/day until progression. After a median follow-up of 17 months, the median overall survival was not reached for masitinib versus 16 months for sunitinib (Hazard Ratio: 0.27 - 95% CI [0.09; 0.78]). The Overall Survival rate estimates at 6, 12, and 18 months were respectively, 95.7%, 81.9%, and 81.9% in masitinib-treated patients, versus 76.2%, 57.1%, and 42.3% in sunitinib-treated patients. Masitinib was well tolerated, with 17% of patients reporting non-hematological grade 3 related adverse events, as compared with 62% of patients in the sunitinib treatment arm. No patients receiving masitinib reported any related serious adverse events compared with 19% of patients in the sunitinib treatment arm.

Alain Moussy, CEO of AB Science, said “The acceptance of this Marketing Authorization Application by EMA shows that authorities consider masitinib as a potential candidate for registration in this refractory cancer, despite the small size of the phase 2 study."

About GIST

Gastrointestinal stromal tumor (GIST) is a sarcoma, which is a type of cancer that develops in the cells of the body’s connective or supportive tissues. GIST arises within the gastrointestinal tract. It is estimated that approximately 5,000 to 6,000 new patients are diagnosed with GIST each year in the United States. In 2010, the global GIST therapeutics market was valued at $920m and is forecast to grow at a rate of 2% over the next 7 years.

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.

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

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 in veterinary medicine in Europe and in the USA, and is pursuing 10 phase 3 studies in human medicine – including 1 study under analysis in pancreatic cancer, and 8 on-going studies in GIST, metastatic melanoma expressing JM mutation of c-Kit, multiple myeloma, mastocytosis, severe persistent asthma, rheumatoid arthritis, and progressive multiple sclerosis. 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

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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