Paris, 28 July 2014, 8:00 am

Masitinib Treatment of Gleevec®-resistant Gastro-Intestinal Stromal Tumor

Publication in Annals of Oncology

AB Science SA (NYSE Euronext - FR0010557264 - AB), a pharmaceutical company specializing in the research, development and commercialization of protein kinase inhibitors (PKIs), announces the publication of results from a randomized phase 2 study of masitinib in treatment of Gleevec®-resistant gastrointestinal stromal tumor. Entitled, '*Masitinib in advanced gastrointestinal stromal tumor (GIST) after failure of imatinib: a randomized controlled open-label trial*' this article and its accompanying supplementary information are freely accessible online from the peer-reviewed journal Annals of Oncology: http://annonc.oxfordjournals.org/lookup/doi/10.1093/annonc/mdu237.

- **Findings showed masitinib to produce a statistically significant overall survival (OS) advantage of 12.4 months in patients with Gleevec®-resistant GIST when compared with Sutent® (sunitinib) from Pfizer, which is currently the standard of care for second-line treatment of advanced GIST.**

- **Overall, encouraging survival and safety data from a well-controlled and appropriately designed randomized trial indicate a positive benefit–risk balance.**

- **Primary efficacy analysis ensured the masitinib treatment arm could satisfy a prespecified progression-free survival (PFS) threshold. Secondary efficacy analysis showed that masitinib followed by the standard of care generated a statistically significant survival benefit over standard of care.**

- **An international phase 3 trial of masitinib in patients with Gleevec®-resistant/intolerant GIST has been initiated based on these promising results.**

Reported are results of a phase 2 study conducted by Professor Axel Le Cesne (Institut Gustave, Villejuif, France) and colleagues from nine study centers across France. 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. The study met its primary analysis end point, namely, that the lower bound of the 90% unilateral confidence interval for median PFS (central RECIST) was above a threshold of 3 months for the masitinib treatment arm. Because the primary analysis hypothesis test was conclusive with masitinib, the study was considered a success and further analyses were warranted to evaluate masitinib efficacy and safety. As a secondary analysis, masitinib followed by the standard of care showed a statistically significant survival benefit with respect to standard of care (hazard ratio = 0.27 [0.09–0.85]). Additionally, the safety profile of masitinib was better than that of sunitinib, as evidenced by masitinib-treated patients experiencing less toxicity and reporting a longer time until definite quality of life deterioration.

Professor Olivier Hermine, President of the scientific committee of AB Science and co-author on this publication declared: *"Emerging comprehension about masitinib's secondary mechanisms of action indicates that it differs from those treatments currently available or under development in GIST. There is growing evidence that the long-term survival benefits observed with masitinib treatment in GIST are most likely related to its ability to stimulate an innate immune response and induce changes in the tumor microenvironment, the benefit of which is to extend survival by controlling the aggressiveness, transformation and dissemination of the tumors. Taken together with the various external and internal*

sources of validation described in this paper, there is a strong biological plausibility for the use of masitinib in imatinib-resistant GIST, which in turn is supported by these clinical data".

Professor Antoine Adenis (Centre Oscar Lambret, Lille, France) lead author of this publication commented: "*The key message from these findings is that when considered in the setting of effective subsequent therapies, adding masitinib to the armaterium of drugs used to treat GIST generated a clinically relevant survival benefit. A larger phase 3 randomized clinical trial is currently recruiting patients in this indication to confirm these encouraging results."*

Summary of the phase 3 trial in progress

An international phase 3 trial of masitinib in patients with Gleevec®-resistant/intolerant GIST has been initiated based on these promising results. The objectives of this study are to reaffirm that masitinib has a superior safety profile to that of sunitinib in this population and also to confirm the observed survival benefits of administering masitinib in the second-line setting. This study will enroll approximately 208 patients (104 patients per treatment-arm). The primary response evaluation will be overall survival.

About gastrointestinal stromal tumor

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.

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'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.

* * *

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