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AB Science reports phase 3 study results of masitinib in combination with Gemzar® for treatment of pancreatic cancer.

European Medicines Agency accepts Marketing Authorization Application for conditional approval of masitinib in the treatment of pancreatic cancer.

AB Science SA (NYSE Euronext - FR0010557264 - AB), a pharmaceutical company specializing in the research, development and commercialization of protein kinase inhibitors, announced today the results from a phase 3 study evaluating the effect of masitinib in combination with Gemzar® (gemcitabine, Eli Lilly and Company) on overall survival (OS) in patients with pancreatic cancer. Briefly, masitinib in combination with Gemzar® significantly extended median OS by 6 and 2.7 months in two independent patient populations, representing 65% and 45% of the overall population; namely, patients with a genetic biomarker - collected from simple blood sample - indicative of aggressive disease progression, and patients with cancer pain. Pain intensity and the discovered genetic biomarker were shown to be of prognostic value for survival under Gemzar® alone and at the same time predictive of increased survival with masitinib in combination with Gemzar® for those patients identified as having a poor prognosis with Gemzar® alone.

AB Science also announced that the European Medicines Agency (EMA) has accepted to review a Marketing Authorization Application (MAA) for conditional approval of masitinib in combination with Gemzar® in the treatment of pancreatic cancer, following filing of this dossier.

Full data has been submitted for presentation at the American Society of Clinical Oncology (ASCO) Gastrointestinal Cancers Symposium (24-26 January 2013, in San Francisco, California).

Filing for the conditional approval of masitinib in combination with Gemzar® in the treatment of non resectable, advanced adenocarcinoma pancreatic cancer was accepted by EMA on the basis of results from a phase 3 study that showed masitinib in combination with Gemzar® significantly extends overall survival in two independent patient populations having the worst prognosis. These populations consisted of patients with a gene expression profile (or genetic biomarker) indicative of aggressive disease progression (65% of pancreatic cancer patients), and patients with cancer pain (45% of pancreatic cancer patients). In this prospective, international, randomized, double-blinded clinical trial, 348 patients received either masitinib in combination with Gemzar®, or placebo in combination with Gemzar®. A planned ancillary pharmacogenomic study, based on RNA extracted from whole blood samples before treatment start, was also conducted to identify genetic expression patterns predictive for overall survival and/or treatment benefit.

AB Science made two important discoveries based on data from these studies.

- First, pancreatic cancer patients characterized by the discovered genetic biomarker (approximately 65% of all patients) reported very poor survival when receiving placebo plus Gemzar®, with a median OS of 5 months. However, this same genetic biomarker was highly predictive of significantly extended survival in patients receiving masitinib in combination with Gemzar®, with a median OS increased by 6.0 months to 11.0 months, corresponding to a hazard ratio of 0.29 (p=0.000038). OS rates at 12 and 18 months were respectively, 41.4% and 18.5% in the masitinib plus Gemzar® treatment arm versus 11.1% and 4.2% in the placebo plus Gemzar® arm.

- Second, patients presenting with a certain threshold of pain intensity at the time of study entry (approximately 45% of all patients) were revealed to have a very poor prognosis when receiving placebo plus Gemzar®, with a median OS of 5.4 months. In these patients, the combination therapy

of masitinib plus Gemzar® showed a statistically significant extended survival, with median OS increased by 2.7 months to 8.1 months, corresponding to a hazard ratio of 0.61 (p=0.010). OS rates at 12 and 18 months were respectively, 32.2% and 18.2% in the masitinib plus Gemzar® treatment arm versus 17.8% and 7.8% in the placebo plus Gemzar® arm.

Besides being predictive for masitinib plus Gemzar® treatment efficacy, these two factors were also of prognostic value for overall survival in patients treated with Gemzar® as a single agent. Regarding the genetic biomarker, patients harboring this 'aggressive genetic fingerprint' had a median OS of 5.0 months whilst patients without this fingerprint had a median OS of 14.3 months. Regarding the prognostic factor of 'pain intensity', patients exceeding a certain threshold of pain at baseline had a median OS of 5.4 months versus 15.4 months in patients without pain.

Results in the overall study population did not show a significant advantage for masitinib in combination with Gemzar® as compared with Gemzar® treatment alone. Median OS was 7.7 months in the masitinib plus Gemzar® treatment arm versus 7.0 months in the placebo plus Gemzar® treatment arm (p=0.74; hazard ratio=0.90). This finding of a non significant survival improvement in the overall population is explained by the fact that masitinib is not indicated when Gemzar® is highly efficient; namely, the situation defined by an absence of both pain and genetic biomarker detecting "aggressiveness".

Olivier Hermine, MD, PhD, President of the Scientific Committee of AB Science commented: *"The prognostic factors of 'pain intensity' and 'aggressive genetic fingerprint' revealed by AB Science are two major discoveries in this devastating disease that has a high unmet medical need. We previously knew that pain was correlated with poor prognosis in pancreatic cancer. Our current working hypothesis is that pain flags the presence of mast cells in the tumor microenvironment and mast cell activation may help transform the tumors into a more aggressive form. On the other hand, the genetic biomarker is really revolutionary since it would be the first time that RNA expression from whole blood samples is capable of predicting overall survival in patients depending upon the treatment received. In addition, this genetic biomarker could be used as a prognostic tool: patients with the 'aggressive genetic fingerprint' and receiving the standard treatment of Gemzar® monotherapy had a median OS of only 5 months, whilst patients without this genetic biomarker survived on average for 14.3 months. It is encouraging that masitinib seems to improve significantly survival in patients with the worst prognosis and who represent the highest unmet medical need".*

Alain Moussy, CEO of AB Science declared: *"We knew that masitinib had an antimetastatic potential thanks to our recent GIST study as 2nd line treatment in Gleevec-resistant patients. That study revealed masitinib did not outperform sunitinib, the current 2nd line treatment for GIST, in terms of PFS (progression-free survival) but did significantly improve median OS with a hazard ratio of 0.29. The pancreatic cancer phase 3 study delivers a second clinical proof of masitinib's antimetastatic effect in cancer, again showing comparable PFS between treatment arms whilst overall survival was significantly increased in two independent subpopulations. In patients with 'pain' median OS was increased by 2.7 months with a corresponding hazard ratio of 0.61, and in patients with the 'aggressive genetic fingerprint' median OS was improved by an impressive 6.0 months with a hazard ratio of 0.29, when treated with the masitinib plus Gemzar® combination. It seems that the inhibition of mast cell activity in cancer is one of the key drivers of masitinib. However, masitinib evidently does more since other tyrosine kinase inhibitors of mast cells have failed in the pancreatic cancer or GIST indications. Masitinib seems to touch key pathways that are involved with metastatic progression in cancer, the very mechanism which eventually leads to death".*

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

About Pancreatic cancer

Incidence of pancreatic cancer has markedly increased over the last few decades with more than 230,000 patients worldwide diagnosed with this condition. Patients diagnosed with pancreatic cancer often have a poorer prognosis compared with other cancers in part because early detection is difficult. At the time of diagnosis, most patients with

pancreatic ductal adenocarcinoma present with locally advanced or metastatic disease and only 10-20% of cases are candidates for curative surgery. Median overall survival from diagnosis is around 3 to 6 months; 5-year survival is much less than 5% and complete remission is extremely rare [American Cancer Society, 2008].

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 8 on-going phases 3 studies in human medicine 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

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