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AB Science announces CHMP has adopted a negative opinion for the conditional approval of Masitinib in the treatment of pancreatic cancer

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 negative opinion for the conditional approval of Masiviera (Masitinib mesylate) for the first-line treatment of non-resectable locally advanced or metastatic pancreatic cancer.

The CHMP mentions three concerns that create uncertainties, which are i) the failure of the study in the overall population and the need to confirm the benefit in the subgroups since according to CHMP the study was not designed to show benefit in these smaller groups, ii) the increased toxicity of the combination of masitinib and gemcitabine as compared to gemcitabine alone, and iii) concerns about the quality of the product, and in particular that patient exposure to impurities is insufficiently controlled and that the reproducibility between clinical and commercial batches cannot be guaranteed.

Although AB Science considers that the subgroup analysis was sufficiently documented, AB Science recognizes the challenge to register a drug in subgroups when the test on the overall population failed, even if this situation is not unprecedented, especially in the context of a conditional approval. Yet, AB Science will appeal this decision for the following reasons.

The main reason is that not only pancreatic cancer represents an important need in medicine but the two subgroups where masitinib is efficient, patients with pain and patients with aggressive genomic biomarker (aggressive GBM) represent an even more urgent need since the median survival is shorter than in the overall population with 5 months median survival. With masitinib, survival was extended to 8 months for patients with pain (P value = 0.012) and 13 months in the aggressive GBM (p value = 0.0000001).

The second reason is that the findings in the two subgroups are consistent with the known mechanism of action of masitinib able to boost and modulate the innate immune system.

The third reason is that none of the existing therapies, Tarceva, Folfirinox or Abraxane fulfill the need in the proposed populations, population with pain and patients with poor survival detected by a genomic marker.

Regarding the increased toxicity, it is expected that the combination of masitinib and gemcitabine will increase the frequency and severity of adverse events as compared to gemcitabine alone, yet it has been acknowledged that the safety profile would be acceptable in the presence of proven efficacy in the subgroups. Furthermore, the safety profile of masitinib and gemcitabine combination seems acceptable in light of the observed toxicity of alternative combination of chemotherapies.

Regarding the quality concerns, they are the same as the ones listed by CHMP for GIST. They have either been resolved (lowering of acceptable threshold of control for impurity level) or are in the process of being resolved through appropriated complementary studies.

This appeal should lead the CHMP to deliver a second opinion in the course of 2014.

AB Science points out that what is at stake is the acceleration of the approval under condition of a confirmatory study and not the full approval, which is targeted after the confirmatory study.

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.

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