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The Data and Safety Monitoring Board recommends continuation of the phase 2 study assessing masitinib in relapsing head and neck cancer based on safety and efficacy data

AB Science SA (NYSE Euronext – FR0010557264 – AB), a pharmaceutical company specialized in research, development and marketing of protein kinase inhibitors (PKIs), announces that the external Data and Safety Monitoring Board (DSMB) has recommended continuation of its phase 2 study assessing masitinib in second or third line of treatment of head and neck squamous cell carcinoma based upon review of the latest safety and efficacy data. The DSMB was created as part of the Company's clinical study evaluating masitinib in the treatment of head and neck squamous cell carcinoma.

The objective of this phase 2 study is to evaluate the safety and efficacy of masitinib in combination with irinotecan or masitinib in combination with gemcitabine in patients with a recurrent and/or metastatic head and neck squamous cell carcinoma in second or third line of treatment. The study's primary endpoint is overall survival.

There are three objectives:

i) To determine if masitinib can be safely combined with chemotherapy in this indication.

ii) To determine if the study meets the pre-defined statistical hypothesis to detect a trend of superiority on OS as compared with the latest benchmark in this indication. This statistical test is based on the upper bound for the confidence interval of Hazard Ratio, estimated from the median OS observed in this phase 2 study and the historical benchmark.

iii) To determine which combination has the best benefit-risk balance if any.

Achieving these three objectives is considered a prerequisite for progressing into phase 3 development.

This recommendation from the DSMB is encouraging because it confirms that the safety for the combination of masitinib with irinotecan or gemcitabine is acceptable based on the data currently generated in this study.

"Patients with relapsing head and neck squamous cell carcinoma have very few treatment options to help them manage their disease" said Jérôme Fayette, M.D., principal Investigator of the study and Clinical Investigator with Centre Léon Bérard, France. *"New treatments are clearly needed, especially those that lead to an increase in median overall survival. We are pleased with the recommended continuation of this phase 2 study, which indicates there are no major safety concerns with the combination and a potential survival benefit trend associated with masitinib's novel mechanism of action and innovative approach to tumor immunotherapy".*

The incidence of head and neck squamous cell carcinoma is reported as approximately 115,000 patients in the USA and Europe[1].

The prognosis is determined by the stage at presentation, established based on the extent of the tumor, as well as the presence of lymph-node metastases and distant metastases. About one third of patients presents with early-stage disease, whereas two thirds present with advanced cancer with lymph node metastases. Early-stage tumors are treated with surgery or radiotherapy and have a favorable prognosis. The standard of care for the remaining two thirds advanced tumors is surgery combined with adjuvant

[1] http://eco.iarc.fr/eucan/Cancer.aspx?Cancer=1; http://seer.cancer.gov/statfacts/html/oralcav.html

radiation therapy and/or chemotherapy. Survival outcomes are poor (40-50% five-year survival rates) for all current therapeutic options.

It is estimated that around 60% of these patients with advanced disease will be eligible for second-line of treatment, depending on their general condition.

With these hypotheses, the number of eligible patients recurrent and/or metastatic head and neck squamous cell carcinoma in second or third line of treatment is estimated to be 45,000 per annum in Europe and the USA.

About masitinib

Masitinib is a new orally administered tyrosine kinase inhibitor that targets mast cells and macrophages, important cells for immunity, through inhibiting a limited number of kinases. Based on its unique 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. In oncology due to its immunotherapy effect, masitinib can have an effect on survival, alone or in combination with chemotherapy. Through its activity on mast cells and consequently the inhibition of the activation of the inflammatory process, masitinib can have an effect on the symptoms associated with some inflammatory and central nervous system diseases and the degeneration of these 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 class of targeted proteins whose action are key in signaling pathways within cells. Our programs target only diseases with high unmet medical needs, often lethal with short term survival or rare or refractory to previous line of treatment in cancers, inflammatory diseases, and central nervous system diseases, both in humans and animal health.

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. The company is currently 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 website: www.ab-science.com.

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