

## The Data and Safety Monitoring Board recommends continuation of the phase 2 study assessing masitinib in relapsing breast 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-line treatment of breast cancer 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 breast cancer.

The objective of this phase 2 study is to evaluate the safety and efficacy of masitinib in combination with gemcitabine or carboplatin or capecitabine in patients with metastatic or locally advanced breast cancer and who had relapsed after first-line chemotherapy. The study's primary endpoint is overall survival.

There are three objectives: to determine if at least one combination has a trend of superiority on overall survival as compared with the latest benchmark in this indication, to determine which combination has the best benefit-risk balance if any and to determine the optimum dose regimen of the masitinib plus chemotherapy combination. 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 benefit-risk balance for masitinib is positive based on the data currently generated in this study.

Pr. Anthony Gonçalves (Institut Paoli-Calmettes, Marseille - France), principal investigator of the study indicated that: "There is a high unmet medical need for patients in second-line treatment of breast cancer, in particular for extending overall survival. For that reason, if masitinib confirmed an acceptable safety profile and showed a trend of increased overall survival as compared with the current benchmark, a phase 3 study could be initiated and masitinib could provide an option for second-line treatment of metastatic or locally advanced breast cancer".

Breast cancer remains the second most common cancer in the world, and kills more women than any other cancer type. The incidence of breast cancer is reported as approximately 600,000 patients in the USA and Europe, and the mortality rate was of 130,000 patients<sup>1</sup>.

85% of patients have breast cancer that is either hormone-receptor positive or HER2 positive.

It is estimated that up to 40% of those diagnosed with breast cancer will develop advanced disease within 10 years. It is also estimated that 60% of patients progressing after first-line treatment of metastatic cancer can receive a second-line of treatment.

With these hypotheses, the number of eligible patients for second-line treatment of metastatic or locally advanced breast cancer is estimated to be 120,000 per annum in Europe and USA.

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<sup>&</sup>lt;sup>1</sup> http://eco.iarc.fr/eucan/; http://seer.cancer.gov/statfacts/html/breast.html

## **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.

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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