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The Data and Safety Monitoring Board recommends continuation of three phase 2 studies assessing masitinib in relapsing liver cancer, breast cancer, and 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 recently recommended, based upon updated safety and efficacy data, continuation of three on-going phase 2 studies assessing masitinib, one in second-line treatment of advanced hepatocellular carcinoma, another in second-line treatment of breast cancer, and the third in second or third-line treatment of head and neck squamous cell carcinoma. The DSMB had previously issued such a recommendation based on an earlier set of data.

Phase 2 in second-line treatment of advanced hepatocellular carcinoma
The objective of this phase 2 study is to evaluate the safety and efficacy of masitinib in combination with etoposide, or masitinib in combination with irinotecan in patients with advanced hepatocellular carcinoma and who relapsed after a first-line therapy with sorafenib. The study's primary endpoint is overall survival.

Phase 2 in second-line 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.

Phase 2 in second or third-line of 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 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.

For each of these studies there are three objectives:

i) To determine if masitinib can be safely combined with chemotherapy in the indication of interest.
ii) To determine if the study meets a pre-defined statistical hypothesis to detect a trend of superiority on OS as compared with the latest benchmark of relevance to each indication. The outcome of this test determines whether or not a confirmatory phase III study should be initiated. This statistical test is considered positive based on the upper bound for the confidence interval of Hazard Ratio being lower than 1, which corresponds to a relative survival benefit for patients in the masitinib treatment-arm.
iii) To determine which of the masitinib-based combinations 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 confirms that the safety for the combination of masitinib with the chemotherapies tested in these indications is acceptable based on the data currently generated from these studies.
This DSMB new recommendation is also consistent with the known mechanism of action for masitinib, which may be capable of generating benefit in survival in various cancers by targeting mast cells and macrophages. There is growing evidence that the long-term survival benefits observed with masitinib treatment 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.

AB Science had previously communicated about the previous opinion from the DSMB on hepatocellular carcinoma (12 November 2014), breast cancer (22 January 2015) and head and neck cancer (30 March 2015).

Targeted patient populations

- Second-line treatment of advanced hepatocellular carcinoma

There is a growing incidence of Hepatocellular carcinoma worldwide. The incidence in 2008 was 86,000 cases in the USA and Europe, with a mortality rate of 78,640 cases. It is estimated that by 2020 the number of cases will reach 105,000 in these geographic locations[1].
Around 40%[2] of patients have advanced Hepatocellular carcinoma (BCLC stage C). These patients have a very poor prognosis and are eligible for first-line treatment with Nevaxar (sorafenib), a multi kinase inhibitor. The median treatment time with sorafenib is around 5.5 months, and the median OS is 9.5 months in BCLC C patients[3].
There is no approved standard in the second-line of treatment and the median OS after failure to sorafenib is around 5 months with currently available therapies. The development of masitinib in this indication therefore addresses a clear unmet medical need.
Around 60% of patients progressing after sorafenib are usually still able to take a second-line of treatment. Based on these numbers the number of eligible patients for second-line treatment of advanced hepatocellular carcinoma is estimated to be 25,000 per annum in Europe and USA by 2020.

- Second-line treatment of 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, with a mortality rate of 130,000 patients[4].
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.

- Second or third-line of treatment of head and neck squamous cell carcinoma

The incidence of head and neck squamous cell carcinoma is reported as approximately 115,000 patients in the USA and Europe[5].
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 present 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 patients with advanced tumors is surgery combined with adjuvant radiation therapy and/or chemotherapy. Survival outcomes are poor in this group (a 5-year survival rate of 40% to 50%) for all current therapeutic options.

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[1] IARC. <http://www-dep.iarc.fr/>; 2011 [accessed 01.11.11].
[2] Journal of Hepatology 2012 vol. 56 j 908–943
[3] N Engl J Med 2008; 359:378–390.
[4] http://eco.iarc.fr/eucan/ ; http://seer.cancer.gov/statfacts/html/breast.html
[5] http://eco.iarc.fr/eucan/Cancer.aspx?Cancer=1; http://seer.cancer.gov/statfacts/html/oralcav.html

It is estimated that around 60% of patients with advanced disease will be eligible for second-line of treatment.
With these hypotheses, the number of eligible patients with 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.

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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