



Paris, July 23, 2018, 7pm

AB Science reports positive IDMC recommendation to continue the study based on a trend analysis of the masitinib phase 2/3 study in refractory metastatic colorectal cancer

AB Science SA (NYSE Euronext – FR0010557264 – AB), a pharmaceutical company specialized in research, development and marketing of protein kinase inhibitors (PKIs), announces the positive recommendation of the Independent Data Monitoring Committee (IDMC) to continue, based on the planned trend-analysis, the study AB12010 in the third and fourth-line treatment of metastatic colorectal cancer.

AB12010 Study design

Study AB12010 is an open-label, randomized, adaptive phase 2/3 study comparing the efficacy and safety of masitinib in combination with FOLFIRI (irinotecan, 5-fluorouracil and folinic acid), versus Best Supportive Care in third or fourth line of treatment of patients with metastatic colorectal cancer.

The patient population consists of patient who are in failure of all available therapies (5FU, irinotecan, oxalplatin +/- bevacizumab, +/- cetuximab, +/- panatumumab or other available combination of chemotherapy) and for which treatment by regorafenib is not recommended. Patients enrolled also need to have a performance status on the ECOG scale inferior or equal to 2.

The study's primary endpoint is Overall survival (OS).

Trend analysis

The study design is an adaptive design. A trend analysis for OS was planned after a certain number of events are observed.

As per protocol, for this trend analysis:

- if the treatment effect (masitinib + Folfiri) is not promising enough, meaning that patients receiving masitinib + Folfiri have a probability of survival increase lower than 25% as compare to patients receiving best supporting care (hazard ratio > 0.75), then the recruitment is stopped
- if the treatment effect (masitinib + Folfiri) is promising enough, meaning that patients receiving masitinib + Folfiri have a probability of survival increase by more than 25% as compare to patients receiving best supporting care (hazard ratio \leq 0.75), then the recruitment is carried on and the final sample size is calculated so that if the trend persists, the study can be positive on OS, with an alpha risk of 0.05 and a power greater than 80%.

The trend analysis took place after 42 OS events were recorded. Based on this trend analysis, the IDMC recommended the continuation of the study, with a total of 415 patients to be enrolled.

A total of 190 patients have been enrolled in study AB12010. An interim analysis is planned after around 50% of the total number of required events. AB Science expects study AB12010 to be completed in 2019.

Intended claim

The intended claim for masitinib in colorectal cancer is for the treatment in combination with Folfiri of patients with metastatic colorectal cancer, in failure to Folfax and Folfiri, and not eligible to regorafenib (Stivarga®) or trifluridine (Lonsurf®).

Patients in third or fourth line of treatment account for about 20% of the colorectal cancer population at any point in time meaning that such cases represent 80/100,000 of the population, i.e. around 250 000 patients in the USA and 400 000 patients in Europe.

There is no registered product in the intended claim.

About Colorectal cancer (CRC)

Colorectal cancer (CRC) is the third most common cancer in men and the second most common cancer in women worldwide (Globocan 2012). In Europe, CRC is the most frequently diagnosed cancer and the second leading cause of cancer death. CRC was responsible for 215 000 deaths in Europe in 2012.

The stage of disease at the time of diagnosis represents the most relevant prognostic factor. Five-year survival rates range from 93% for stage I disease to less than 10% for stage IV.

Surgery, followed by adjuvant chemotherapy in certain cases, represents the standard therapeutic approach for patients with loco-regional disease. However, approximately 25% of patients present with metastases at initial diagnosis and almost 50% of patients with CRC will develop metastases, contributing to the high mortality rates reported for CRC. The CRC-related 5-year survival rate approaches 60%.

At present, there is no curative treatment for patients with mCRC. When left untreated, patients have a poor prognosis, with a median survival of about 6 months. With the exception of few selected patients where resection of metastases is indicated, the standard treatment for patients with metastatic disease is represented by systemic chemotherapy, which has demonstrated to significantly improve overall survival to an average of 20 months.

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 microglia 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.

AB Science has developed a proprietary portfolio of molecules and the Company's lead compound, masitinib, has already been registered for veterinary medicine and is developed in human medicine in oncology, neurological diseases, and inflammatory diseases. 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.

Forward-looking Statements - AB Science

This press release contains forward-looking statements. These statements are not historical facts. These statements include projections and estimates as well as the assumptions on which they are based, statements based on projects,

objectives, intentions and expectations regarding financial results, events, operations, future services, product development and their potential or future performance.

These forward-looking statements can often be identified by the words "expect", "anticipate", "believe", "intend", "estimate" or "plan" as well as other similar terms. While AB Science believes these forward-looking statements are reasonable, investors are cautioned that these forward-looking statements are subject to numerous risks and uncertainties that are difficult to predict and generally beyond the control of AB Science and which may imply that results and actual events significantly differ from those expressed, induced or anticipated in the forward-looking information and statements. These risks and uncertainties include the uncertainties related to product development of the Company which may not be successful or to the marketing authorizations granted by competent authorities or, more generally, any factors that may affect marketing capacity of the products developed by AB Science, as well as those developed or identified in the public documents filed by AB Science with the Autorité des Marchés Financiers (AMF), including those listed in the Chapter 4 "Risk Factors" of AB Science reference document filed with the AMF on November 22, 2016, under the number R. 16-078. AB Science disclaims any obligation or undertaking to update the forward-looking information and statements, subject to the applicable regulations, in particular articles 223-1 et seq. of the AMF General Regulations.

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