Paris, June 12, 2019, 7.45pm

Interim results for confirmatory masitinib study in pancreatic cancer with pain

IDMC recommends to continue study.
Chance of success above 80% in patients with locally advanced tumors if remaining patients follow a similar pattern to those analyzed at the interim analysis

Company to host webcast on masitinib in pancreatic cancer

AB Science SA (NYSE Euronext - FR0010557264 - AB) announces the positive recommendation of the Independent Data Monitoring Committee (IDMC), following the interim analysis of study AB12005 in the first-line treatment of pancreatic cancer.

A webcast will be hosted on 14 June 2019 at 5.45 pm (CET). To participate please email at contact@ab-science.com.

AB12005 study design and status

Study AB12005 is an international, randomized, placebo-controlled, phase 3 confirmatory study of masitinib in first-line treatment of unresectable locally advanced or metastatic pancreatic cancer patients with pain at baseline or taking opioids.

The study compares the efficacy and safety of masitinib in combination with gemcitabine to placebo in combination with gemcitabine.

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

The number of patients planned for enrolment was 330 patients, with patient recruitment having now been completed.

The efficacy assessment is planned in the overall study population and in the pre-specified subgroup of patients with unresectable locally advanced tumors with pain.

The distinction between unresectable locally advanced or metastatic disease status was a stratification factor, thereby ensuring that treatment-arms are unbiased for this known prognostic factor.

Interim analysis performed by the Independent Data Monitoring Committee (IDMC)

An interim analysis performed by the Independent Data Monitoring Committee (IDMC) was pre-planned once 50% of the events (in this case, patient death) had been reached.

The interim analysis tests futility and conditional power ≥80% (i.e. probability of success). The protocol prospectively defines the following scenarios based on findings of the interim analysis: a) stop the study if futile; b) continue the study because test with conditional power ≥ 80% is met, with or without resampling;

c) in between the two abovementioned scenarios. It is scenario (b) that would make interim analysis decisive for study continuation.

In the pre specified subgroup of patients with unresectable locally advanced tumors, the IDMC recommended continuation without resampling, corresponding to scenario (b). In the overall population, interim data corresponds to scenario (a) or (c). The IDMC considered that it was not necessary to distinguish between those two scenarios because patient enrolment was complete at the time of the interim analysis. The IDMC did not recommend to discontinue any patient.

Based on the rules set for the interim analysis, the interpretation is that the probability of success of study AB12005 is above 80% in the selected sub-population, assuming that the remaining surviving patients follow a similar pattern to those analyzed at the interim analysis.

AB Science expects to report the final results from study AB12005 in 2020.

Rationale for developing masitinib in patients with pancreatic cancer with pain

A first phase 2/3 study enabled the identification of a subgroup based on the level of pain at baseline where survival was statistically increased (+2.6 months, p=0.012, Hazard Ratio=0.62[0.43;0.89]). Pain intensity was assessed via a visual analog scale (VAS) at baseline. This linear scale provides a visual representation of pain as perceived by the patient. Pain intensity was represented by a 100 mm long, continuous line free of any internal reference marks. One extremity indicated an absence of pain (0-value) and the other extremity indicated very severe pain (100-value). The VAS threshold for the 'pain' subgroup was set to VAS ≥20 mm, which is consistent with established precedent from the scientific literature [1-5].

If study AB12005 shows a survival benefit, either in the subgroup of locally advanced pancreatic cancer or in the overall study population, it will corroborate this previous finding and therefore, can be considered as a confirmatory study.

There is evidence from the scientific literature in support of biological plausibility for the observed masitinib treatment-effect in patients with baseline pain (VAS ≥ 20). The presence of pain in pancreatic cancer is thought to flag an increased mast cell activity within the tumor microenvironment, which promotes disease progression. Masitinib's highly selective inhibition of mast cell activation is expected to be of therapeutic benefit by modulating mast cell related remodeling of the tumor microenvironment.

About pancreatic cancer

The estimated prevalence of people living with pancreatic cancer is 21 per 100,000 [6]. At the time of diagnosis, most patients with pancreatic ductal adenocarcinoma present with locally advanced or metastatic disease and only 10-20% of cases are candidates for curative surgery. Median overall survival is between 6 to 7 months and 1-year survival rates range between 17 to 25% [7;8]. As such, population with non-resectable pancreatic cancer in first line is around 100,000 in the EU and 60,000 in the USA.

Almost all patients experience pain in pancreatic cancer in the course of their disease. From the first study, around 50% of patients with pancreatic cancer had pain intensity (VAS > 20) or take opioids at baseline.

At least 50% of pancreatic cancer patients are patients with unresectable locally advanced tumors [9].

Reference

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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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