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AB Science reports positive IDMC recommendation based on an interim analysis of the masitinib phase 3 study in first-line treatment of castrate resistant prostate 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), following the interim analysis of study AB12003 in the first-line treatment of metastatic castrate resistant prostate cancer (mCRPC).

AB12003 Study design

Study AB12003 is an international, multicenter, randomized, double blind, placebo-controlled, 2-parallel groups, phase 3 study in first-line metastatic castrate resistant prostate cancer (mCRPC).

The patient population consists of adult males who have progressed to develop castration-resistant prostate cancer (CRPC) after castration treatment (reduction of available androgen/testosterone/DHT by chemical or surgical means). These are considered to be patients in the first-line metastatic castration-resistant prostate cancer (mCRPC).

The study compares in these patients the efficacy and safety of masitinib in combination with docetaxel to placebo in combination with docetaxel. Docetaxel is combined with prednisone according to usual practice.

The study's primary endpoint is progression free survival (PFS).

Olivier Hermine, Chairman of AB Science Scientific Committee and member of the French Académies des Science, indicated *"There is still a need for more effective first-line treatment of mCRPC. Docetaxel remains the standard treatment in this indication. Recent therapies approved for CRPC are drugs used either prior to chemotherapy with docetaxel, such as sipuleucel-T (Provenge), abiraterone acetate (Zytiga), and enzalutamide (Xtandi), or used for non-metastatic prostate cancer (apalutamide (Erleada)). Masitinib is positioned in combination with docetaxel after failure of hormone therapy"*.

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 had been reached.

Based on results from this interim analysis, the IDMC has recommended the continuation of study AB12003 in a pre-specified sub-population of patients that were identified based on a specific biological biomarker of disease aggressiveness, and estimated to account for about two-third of the eligible population. A total of 468 patients are to be enrolled in this sub-population, while enrolment of patients with an absence of this biomarker will be stopped.

Based on the rules set for the interim analysis, this recommendation from the IDMC means that the probability of success of study AB12003 is above 80% in the selected sub-population, assuming that the patients remaining to be enrolled behave similarly to those analyzed at the interim analysis.

AB Science expect study AB12003 to be completed in 2019.

About castrate resistant prostate cancer (CRPC)

Prostate cancer is the most common cause of cancer in men, with 137.9 new cases per 100,000 men per year [1]. There were an estimated 1.6 million new cases diagnosed worldwide in 2015 and the American Cancer

Society estimates that in the US 164,690 new cases of prostate cancer will be diagnosed in 2018 [2,3]. In the European Union, the estimated number of new prostate cancer cases in 2015 was 365,000 [4].

Development of prostate cancer is often driven by male sex hormones called androgens, including testosterone. Castrate-resistant prostate cancer occurs when prostate cancer grows despite the use of androgen-deprivation therapy to block the action of male sex hormones. Metastatic CRPC (mCRPC) occurs when the cancer spreads to other parts of the body. Castrate-resistant prostate cancer is defined by disease progression despite androgen depletion (hormone) therapy and may present as either a continuous rise in serum prostate-specific antigen (PSA) levels, the progression of pre-existing disease, and/or the appearance of new metastases.

Prostate cancer is also the second most common cause of cancer death in men, with the highest rates being in North America, Australia, and Northern and Central Europe [2]. Although the overall 5-year survival rate for prostate cancer is very high, up to 20% of men who undergo state-of-the-art treatment for prostate cancer will develop CRPC within 5 years, and at least 84% of these will have metastases at the time of CRPC diagnosis [1]. Likewise, almost all patients with metastatic disease become resistant to androgen-deprivation therapy. Median survival for those with mCRPC ranges from approximately 15 to 36 months in recent studies, and 5-year survival is only 28% [1].

References

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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 ABSience

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.

For additional information, please contact:

ABScience

Financial Communication & Media Relations

investors@ab-science.com