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FDA green-lights U.S. patient enrollment in masitinib Phase 3 study following IND clearance in metastatic castrate-resistant prostate cancer eligible to chemotherapy

Topline results expected to be available by end of 2020

AB Science SA (NYSE Euronext - FR0010557264 - AB) today announces that the U.S. Food and Drug Administration (FDA) has cleared the company's Investigational New Drug (IND) application to conduct its masitinib Phase 3 study (AB12003) in metastatic castrate-resistant prostate cancer (mCRPC) eligible to chemotherapy.

Study AB12003 is an international, multicenter, randomized, double blind, placebo-controlled, 2-parallel group, Phase 3 study in metastatic castrate resistant prostate cancer (mCRPC) eligible to chemotherapy. The study aims to compare the efficacy and safety of masitinib (6.0 mg/kg/day) in combination with docetaxel to placebo in combination with docetaxel. Docetaxel is combined with prednisone.

The study primary endpoint is progression free survival (PFS). A total of 468 patients are planned to be enrolled.

The target patient population consists of adult males who have progressed to develop metastatic castrate resistant prostate cancer (mCRPC) after castration treatment (i.e. reduction of available androgen/testosterone/DHT by chemical or surgical means) and are therefore eligible for chemotherapy.

An interim analysis was performed by the Independent Data Monitoring Committee (IDMC) in June 2018. Based on the rules set for the interim analysis, the recommendation from the IDMC was to continue the study in a pre-specified subgroup of patients that are identified by a biomarker. According to the statistical rule of the protocol at the interim analysis, this means that the probability of success of study AB12003 may exceed 80% in this pre-specified subgroup, assuming that the patients remaining to be enrolled behave similarly to those analyzed at the interim analysis. The subgroup of patients is expected to represent around two-thirds of the population.

AB Science expects the topline results from the trial to be available by end of 2020.

About castrate-resistant prostate cancer (CRPC)

Development of prostate cancer is often driven by male sex hormones called androgens, including testosterone. Castrate-resistant prostate cancer (CRPC) 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. Metastatic CRPC (mCRPC) occurs when the cancer spreads to other parts of the body.

Prostate cancer is the most common cause of cancer in men, with 137.9 new cases per 100,000 men per year [1]. The estimated prevalence of people living with prostate cancer is 113 per 100,000 [2], with approximately 15% of the patients having metastatic castrate-resistant prostate cancer (mCRPC) eligible to chemotherapy [3]. As such, population with metastatic castrate-resistant prostate cancer (mCRPC) eligible to chemotherapy is around 75,000 in the EU and 50,000 in the USA.

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. 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]. Practically 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
[1] Crawford ED, Petrylak D, Sartor O. Navigating the evolving therapeutic landscape in advanced prostate cancer. Urol Oncol. 2017 May;35S:S1-S13. doi: 10.1016/j.urolonc.2017.01.020.
[2] Bray F, Ferlay J, Soerjomataram I, Siegel RL, Torre LA, Jemal A. Global cancer statistics 2018: GLOBOCAN estimates of incidence and mortality worldwide for 36 cancers in 185 countries. CA Cancer J Clin. 2018;68(6):394–424.
[3] Scher 2015 – PLoSONE - Symptomatic mCRPC that has not been treated with or not progressed on chemotherapy

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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