



## PRESS RELEASE

### **PHASE 2B/3 STUDY EVALUATING MASITINIB IN IN METASTATIC CASTRATE-RESISTANT PROSTATE CANCER (MCRPC) MET ITS PRIMARY ENDPOINT**

*Paris, 29 April 2021, 7pm CET*

**AB Science SA** (Euronext - FR0010557264 - AB) today announced that its masitinib Phase 2B/3 study (AB12003) in metastatic castrate-resistant prostate cancer (mCRPC) eligible to chemotherapy met its predefined primary endpoint.

Patents related to study AB12003 results are being filed and detailed results of study AB12003 will be presented during a webcast with Key Opinion Leaders that will be held as soon as patents have been filed.

#### **About study AB12003**

Study AB12003 was 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 aimed to compare the efficacy and safety of masitinib (6.0 mg/kg/day) in combination with docetaxel versus placebo in combination with docetaxel. Docetaxel was combined with prednisone.

The study primary endpoint was progression free survival (PFS).

The target patient population consisted of adult males who had 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 were therefore eligible for chemotherapy.

#### **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](http://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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