PRESS RELEASE

MASITINIB RECEIVES FDA AND EMA AUTHORIZATION FOR CONFIRMATORY PHASE 3 TRIAL IN METASTATIC CASTRATE-RESISTANT PROSTATE CANCER, WITH BIOMARKER-DRIVEN PATIENT SELECTION TARGETING POPULATION MOST LIKELY TO BENEFIT

Paris, July 4, 2025, 8am CET

AB Science SA (Euronext - FR0010557264 - AB) today announced that a confirmatory phase 3 trial of masitinib in metastatic castrate resistant prostate cancer (study AB22007) has been authorized by FDA and EMA (harmonized protocol approved through step 1 of Clinical Trials Information System), with a biomarker that targets patients with less advanced metastatic disease.

Professor Olivier Hermine, MD, President of the Scientific Committee of AB Science and member of the Académie des Sciences in France said, "*The authorization of our confirmatory Phase 3 study by both the FDA and EMA represents a critical milestone for masitinib in metastatic castrate-resistant prostate cancer. With a validated biomarker guiding patient selection, this trial has the potential to establish the first targeted combination with docetaxel in nearly two decades for mCRPC.*"

- **Design of phase 3 study**

Study AB22007 is a prospective, multicenter, randomized, double blind, placebo-controlled, 2-parallel groups, phase 3 study to confirm the efficacy and safety of docetaxel (IV 75 mg/m² plus prednisone for up to 10 cycles) plus masitinib 6.0 mg/kg/d, versus docetaxel plus placebo in metastatic castrate resistant prostate cancer (mCRPC).

The study will enroll 600 patients (randomization 1:1) with confirmed mCRPC eligible to docetaxel and with a biomarker (as measured by baseline alkaline phosphatase level) indicative of less advanced metastatic disease. The study's primary endpoint will be radiographic progression free survival (rPFS), supported by overall survival as the first secondary endpoint.

- **Masitinib is positioned in metastatic castrate resistant prostate cancer eligible to docetaxel, a high unmet medical need**

Masitinib is positioned in combination with docetaxel as a treatment of mCRPC patients who are eligible to docetaxel; that is to say, it is administered directly following resistance or relapse after the metastatic hormone-sensitive prostate cancer (mHSPC) treatments.

While there are numerous treatments in the mHSPC treatment space, there is currently no drug registered for use in combination with standard of care treatment docetaxel in patients who have relapsed on hormone treatments, i.e., patients with mCRPC, despite docetaxel having been approved almost 20 years ago.

Although localized disease is associated with high survival rates, metastatic prostate cancer still represents an unmet medical need with a 5-years survival rate of about 30% [1]. 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 [2]. Practically all patients with metastatic disease become resistant to androgen-deprivation therapy.

Prostate cancer is the most common cause of cancer in men, with 137.9 new cases per 100,000 men per year [2]. The estimated prevalence of people living with prostate cancer is 113 per 100,000 [3], with approximately

15% of the patients having mCRPC eligible to chemotherapy [4]. As such, the population with mCRPC eligible to chemotherapy is around 75,000 in the EU and 50,000 in the USA.

- **Results from study AB12003 demonstrated that the biomarker Alkaline Phosphatase predicts response of masitinib in mCRPC. The combination of masitinib plus docetaxel may provide a new first-line treatment option for mCRPC patients with low metastatic involvement**

Primary analysis:

AB12003 was a prospective, placebo controlled, double blind, randomized, phase 3 trial, evaluating masitinib (6.0 mg/kg/d) in combination with docetaxel (IV 75 mg/m² plus prednisone for up to 10 cycles) as a first-line treatment of mCRPC. Eligible patients were chemo-naïve with confirmed mCRPC, who had progressed on previous abiraterone treatment or were indicated for docetaxel treatment, and had a ECOG ≤1. Primary analysis was performed on a pre-specified targeted subgroup, defined as patients with baseline alkaline phosphatase levels (ALP) ≤250 IU/L, and on the overall population. Primary endpoint was progression free survival (PFS) (PCWG2 definition). The study was successful if improvement in median PFS relative to control reached a 3.9% level of significance for the target subgroup (alpha split with fallback procedure to conserve overall type-I error at 5% for the overall study cohort). Primary analysis was based on 450 patients in the targeted subgroup (ALP ≤ 250 IU/L). There was a total of 712 patients in the overall study cohort.

Masitinib (6.0 mg/kg/day) plus docetaxel confers a significant PFS benefit in mCRPC patients with ALP ≤ 250 IU/L. Hazard ratio of 0.79 [0.64;0.97] (p=0.0087), corresponding to a 21% reduction in risk of progression relative to control. Assessment of PFS rates was convergent with this primary outcome; 12, 18, and 24-month PFS rates showed significant improvement in favor of masitinib plus docetaxel relative to control: 1.6-fold (p=0.0035), 1.9-fold (p=0.0001) and 1.9-fold (p=0.0028), respectively.

ALP as a biomarker:

Importantly, a progressively greater masitinib treatment effect was observed for lower baseline ALP levels (less advanced metastatic disease), with a significant 47% reduced risk of progression in patients with ALP≤100 IU/L (hazard ratio=0.53, p=0.002).

The efficacy and response of masitinib was in fact correlated to the level of ALP.

The use of biomarker ALP for the confirmatory phase 3 study has been validated by FDA and EMA.

The establishment of a biomarker predictive of the response to masitinib is a potentially important discovery.

ALP measures the involvement in the bones and in the liver of metastasis.

When used sufficiently early, masitinib in combination with docetaxel was able to slow down the progression of the metastatic cancer even resistant to hormone treatments.

The masitinib plus docetaxel safety profile was acceptable with respect to control; consistent with the known masitinib profile and no new safety signals observed.

Historically, there has been a high failure rate of trials studying combinations of docetaxel and new targeted agents, with study AB12003 being a rare example of a phase 3 clinical trial that showed improvement in progression-free survival (PFS) for masitinib in combination with docetaxel.

- **Patent protection until 2042**

Based on the results from AB12003 study, AB Science filed a patent application relating to methods of treating mCRPC (i.e. a secondary medical use patent) with its lead compound masitinib.

The European Patent Office has granted this patent (EP4175639). It provides protection until 2042 for masitinib and related compounds for treatment of mCRPC in the patient subpopulation with low metastatic involvement (as measured by baseline alkaline phosphatase levels), which is the patient population in the

approved phase 3 study of masitinib in mCRPC. Counterpart patent applications have also been filed in other major international markets, including the United States.

References :

[1] Cancer stat facts: prostate cancer. National Cancer Institute/ Surveillance, Epidemiology, and End Results Program. Accessed September 10, 2021. https://seer.cancer.gov/statfacts/html/prost.html
[2] 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.
[3] 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.
[4] Scher 2015 – PLoSONE - Symptomatic mCRPC that has not been treated with or not progressed on chemotherapy

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, inflammatory diseases and viral 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 published by AB Science. 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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