



## PRESS RELEASE

### RESULTS FROM MASITINIB STUDY AB12003 IN PROSTATE CANCER PRESENTED AT THE AMERICAN UROLOGICAL ASSOCIATION ANNUAL MEETING WITH ABSTRACT PUBLISHED IN *JOURNAL OF UROLOGY*

Paris, 13 September, 2021, 6pm CET

**AB Science SA** (Euronext - FR0010557264 - AB) today announced that results from masitinib study AB12003 in metastatic castrate refractory prostate cancer, have been presented as a podium presentation at the 2021 American Urological Association (AUA) Annual Meeting by Dr Michel Pavic (Director of the Hematology and Oncology Unit at University of Sherbrooke, Canada). The AUA Annual Meeting, the largest gathering of urological professionals in the world, was held from September 10–13 as a virtual platform this year.

Masitinib is positioned in combination with docetaxel as a first-line treatment of metastatic Castrate Refractory Prostate Cancer (mCRPC) eligible to chemotherapy. 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% [2]. There is currently no drug registered for use in combination with standard treatment of docetaxel.

*“Results from study AB12003 indicate that the combination of masitinib plus docetaxel may provide a new first-line treatment option for mCRPC patients with low metastatic involvement. This is particularly striking because for years there have been many unsuccessful combination therapy trials with docetaxel in this indication,”* said Michel Pavic, a senior investigator on study AB12003. *“Masitinib represents an innovative approach, being a small molecule drug that targets mast cell and macrophage activity. These are innate immune cells that are increasingly recognized as being critical components of the tumor microenvironment and associated with prostate cancer progression.”*

A prerecorded podium presentation entitled ‘*Masitinib Plus Docetaxel as First-Line Treatment of Metastatic Castrate Refractory Prostate Cancer: Results from Study AB12003*’ was presented on Sunday 12<sup>th</sup> September as part of the Late-Breaking Malignant Abstract Session (LBA02). The abstract has been published in the *Journal of Urology* [1] (<https://www.auajournals.org/doi/10.1097/JU.0000000000002149.11>). Highlights from the presentation included:

- Masitinib (6.0 mg/kg/day) plus docetaxel confers a significant PFS benefit in mCRPC patients with ALP ≤ 250 IU/ml. 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.
- 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/mL (hazard ratio=0.53, p=0.002).
- No PFS benefit was observed for the overall population.
- The masitinib plus docetaxel safety profile was acceptable with respect to control; consistent with the known masitinib profile (neutropenia, anemia, diarrhea, and skin reactions) with no new safety signals observed.

## **AB12003 Study Design**

AB12003 was a prospective, placebo controlled, double blind, randomized, phase 3 trial, evaluating MAS (6.0 mg/kg/d) in combination with docetaxel (IV 75 mg/m<sup>2</sup> plus prednisone for up to 10 cycles) as a first-line treatment of metastatic castrate resistant prostate cancer (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/ml, 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/ml). There was a total of 712 patients in the overall study cohort.

## **Reference**

[1] Pavic M, Hermine O, Spaeth D. Masitinib Plus Docetaxel as First-Line Treatment of Metastatic Castrate Refractory Prostate Cancer: Results from Study AB12003. *Journal of Urology*, Volume 206, Issue Supplement 3, September 2021, Page: e1179

[2] 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>

## **About masitinib**

Masitinib is a 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, 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](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 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.

**For additional information, please contact:**

**AB Science**

Financial Communication & Media Relations

[investors@ab-science.com](mailto:investors@ab-science.com)

**Media Relations – USA**

**RooneyPartners**

Kate Barrette

[kbarrette@rooneyco.com](mailto:kbarrette@rooneyco.com)

+1 646 432 0191

**Media Relations – France**

**NewCap**

Arthur Rouillé

[arouille@newcap.fr](mailto:arouille@newcap.fr)

+33 (0)1 44 71 00 15