



**AB SCIENCE RECEIVES NOTICE OF ALLOWANCE FOR EUROPEAN PATENT COVERING MASITINIB IN THE TREATMENT OF METASTATIC CASTRATE REFRACTORY PROSTATE CANCER (mCRPC), STRENGTHENING THE COMPANY'S INTELLECTUAL PROPERTY POSITION UNTIL 2042**

*Paris, 26 June, 2023, 6pm CET*

**AB Science SA** (Euronext - FR0010557264 - AB) today announced that the European Patent Office has issued a Notice of Allowance for a patent relating to methods of treating (mCRPC) with its lead compound masitinib, based on findings from study AB12003 [1]. This new European patent provides intellectual property protection for masitinib in the treatment of mCRPC until 2042.

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

Although there are numerous treatments in the mHSPC treatment space, there is currently no drug registered for use in combination with docetaxel in patients with mCRPC, despite docetaxel having been approved almost 20 years ago. 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.

The Notice of Allowance (NOA) means that the European Patent Office intends to grant the patent application, EP4175639A1, after the completion of certain formal procedural steps. Once granted, the patent can be kept in force until May 2042. A European NOA is issued after an examiner determines that a patent application satisfies all requirements for patentability under the European Patent Convention.

More specifically, this patent provides protection of masitinib and related compounds for treatment of mCRPC in a patient subpopulation with low metastatic involvement (as measured by baseline alkaline phosphatase levels). This patient population is fully consistent with results from masitinib study AB12003 [1] and the on-going clinical development program of masitinib in mCRPC.

As a reminder, key results from study AB12003 include:

- Masitinib (6.0 mg/kg/day) plus docetaxel conferred a significant progression-free survival (PFS) benefit in mCRPC patients with baseline alkaline phosphatase levels (ALP) less than or equal to 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, with 12, 18, and 24-month PFS rates showing 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 (i.e., less advanced metastatic disease), with a significant 47% reduced risk of progression in patients with ALP less than or equal to 100 IU/L (hazard ratio=0.53,  $p=0.002$ ).
- The masitinib plus docetaxel safety profile was acceptable, consistent with the known masitinib profile and with no new safety signals observed.

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 32% [2].

## **References**

[1] Pavic, Michel; Hermine, Olivier; Spaeth, Dominique LBA02-11 Masitinib plus docetaxel as first-line treatment of metastatic castrate refractory prostate cancer: results from study AB12003, Journal of Urology: September 2021 - Volume 206 - Issue Supplement 3. doi: 10.1097/JU.0000000000002149.11

[2] American Cancer Society. Cancer Facts & Figures 2023. Atlanta: American Cancer Society; 2023. Accessed June 2023. <https://www.cancer.org/content/dam/cancer-org/research/cancer-facts-and-statistics/annual-cancer-facts-and-figures/2023/2023-cancer-facts-and-figures.pdf>

### **About study AB12003**

Study 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/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/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.

### **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.

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