



AB SCIENCE RECEIVES NOTICE OF ALLOWANCE FOR UNITED STATES PATENT COVERING MASITINIB IN THE TREATMENT OF METASTATIC CASTRATE RESISTANT PROSTATE CANCER

THIS POSITIVE DECISION FROM THE USA PATENT OFFICE STRENGTHENS THE COMPANY'S INTELLECTUAL PROPERTY POSITION IN THIS INDICATION UNTIL 2042, ADDING TO THE COVERAGE ALREADY GRANTED IN EUROPE

Paris, January 29, 2026, 6pm CET

AB Science SA (Euronext - FR0010557264 - AB) announced that the United States Patent and Trademark Office (USPTO) issued a Notice of Allowance (NOA) for a patent relating to methods of treating metastatic castrate resistant prostate cancer (mCRPC) with its lead compound masitinib (US 18/040884).

Delivery of masitinib patent in mCRPC

Once granted, this new US secondary medical use patent will provide intellectual property (IP) protection for masitinib in mCRPC until May 2042. A NOA signifies that the USPTO intends to grant the patent application after completing certain formal procedural steps. The US NOA is issued after an examiner confirms that the patent application meets all patentability requirements.

This new US patent adds to the IP coverage already granted in Europe (EP4175639) [1].

Counterpart patent applications have also been filed in other major international markets.

Masitinib positioning in metastatic prostate cancer after failure to hormone therapy

In metastatic prostate cancer, patients take hormone therapies (i.e., androgen-deprivation therapy) in first line and second line. Then when metastatic cancer advances patients have to be treated by chemotherapy. There is only one chemotherapy registered, docetaxel, and no drug in combination with docetaxel or replacement of docetaxel has improved PFS or OS and has been registered for the last 20 years.

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.

Masitinib is one of the rare drugs to have generated positive data on progression free survival (PFS) in combination with docetaxel in this population.

Masitinib positioning in mCRPC with low metastatic involvement measured by a biomarker

More specifically, this patent provides protection for masitinib and related compounds for the 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 the results of the masitinib study AB12003 [2] and the ongoing clinical development program of masitinib in mCRPC.

As a reminder, the 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 the 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 safety profile of masitinib plus docetaxel was acceptable and consistent with the known masitinib profile, with no new safety signals observed.

Unmet medical need in mCRPC

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 approximately 32% [3]. Practically all patients with metastatic disease become resistant to androgen-deprivation therapy.

With 1.5 million new cases and 397,000 deaths worldwide, prostate cancer is the world's second most frequent cancer and the fifth leading cause of cancer death among men [4]. It is estimated that there are at least 3.5 million men living with prostate cancer in the United States [5] and 2.5 million in Europe [6]. Approximately 2% of all prostate cancer cases are mCRPC [7], and practically all patients with metastatic disease will become resistant to androgen-deprivation therapy. As such, the population with mCRPC eligible to chemotherapy is around 50,000 in the EU and 70,000 in the USA.

References

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- [7] Shore N, Oliver L, Shui I, Gayle A, Wong OY, Kim J, Payne S, Amin S, Ghatge S. Systematic Literature Review of the Epidemiology of Advanced Prostate Cancer and Associated Homologous Recombination Repair Gene Alterations. J Urol. 2021 Apr;205(4):977-986. doi: 10.1097/JU.0000000000001570. Epub 2020 Dec 17. PMID: 33332152. <https://www.auajournals.org/doi/10.1097/JU.0000000000001570>

About study AB12003

Study AB12003 was a prospective, placebo-controlled, double-blind, randomized, phase 3 trial that evaluated 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 for metastatic castrate-resistant prostate cancer (mCRPC). Eligible patients were chemotherapy-naïve with confirmed mCRPC, had progressed on previous abiraterone treatment or were indicated for docetaxel treatment, and had an ECOG performance status score of ≤1. Primary analysis was performed on a pre-specified targeted subgroup, defined as patients with baseline alkaline phosphatase (ALP) levels ≤250 IU/L, and on the overall population. The primary endpoint was progression-free survival (PFS) (PCWG2 definition). The study was successful if the improvement in median PFS relative to the control reached a 3.9% level of significance for the target subgroup (alpha split with fallback procedure to conserve the overall type-I error at 5% for the overall study cohort). The primary analysis was based on 450 patients in the targeted subgroup (ALP ≤ 250 IU/L). The overall study cohort comprised 712 patients.

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 is key in signaling pathways within cells. Our programs target only diseases with high unmet medical needs, which are often lethal with short-term survival or rare or refractory to previous lines 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 being developed for human medicine in oncology, neurological diseases, inflammatory diseases, and viral diseases. The company is headquartered in Paris, France and is 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, 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 uncertainties related to the 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 the 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 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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