



**AB SCIENCE RECEIVES NOTICE OF ALLOWANCE FOR EUROPEAN PATENT COVERING MASITINIB UNTIL 2036 IN THE TREATMENT OF MASTOCYTOSIS**

**THIS DECISION FURTHER STRENGTHENS MASITINIB'S INTELLECTUAL PROPERTY PROTECTION STRATEGY BASED ON MEDICAL USE PATENTS**

*Paris, January 15, 2024, 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 severe systemic mastocytosis (i.e. a medical use patent) with its lead compound masitinib, based on findings from study AB06006 [1]. This new European patent provides intellectual property protection for masitinib in this indication until October 2036.

The same medical use patent strategy had been successfully pursued in amyotrophic lateral sclerosis, with patent granted worldwide until 2037, and is being pursued in other indications such as multiple sclerosis, Alzheimer's disease for protection until 2041, and in prostate cancer until 2042.

▪ **Mastocytosis**

Masitinib is positioned as a treatment of severely symptomatic systemic mastocytosis patients, including the subvariants of indolent and smoldering systemic mastocytosis, who are unresponsive to optimal symptomatic treatment.

The Notice of Allowance (NOA) means that the European Patent Office intends to grant the patent application, EP3359195A1, after the completion of certain formal procedural steps. Once granted, the patent can be kept in force until October 2036. 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 systemic mastocytosis in a patient population presenting with at least two severe mast cell mediator release associated symptoms, selected from pruritus, flushes or depression (Hamilton rating scale). This patient population is consistent with results from masitinib study AB06006 [1] and also the on-going clinical development program of masitinib in severe systemic mastocytosis.

*"This is good news because it proves once again that the masitinib platform is protected for a period of between 12 to 17 years depending on the indication, providing enough time to complete the program until registration and to maximize revenues during the commercialization phase",* said Alain Moussy, CEO of AB Science.

Masitinib has previously been granted orphan drug status in mastocytosis by the FDA and the EMA.

▪ **Other Indications**

The same medical use patent strategy had been successfully pursued in amyotrophic lateral sclerosis (ALS), with a patent relating to with the treatment of ALS with masitinib having been granted in 14 regions to date: namely, Europe (patent EP 3240538), USA (US 10092564), Canada (CA 3018635), China (ZL201780019760.9), South Korea (KR 10-2293847), Japan (JP 7250312B2), Israel (IL 261856), Australia (AU M53001274), Eurasia (EA 201800499), Mexico (MX 390495), Singapore (SG 11201808106Y), New Zealand (NZ 745778), South Africa (ZA 2018/05810), and Hong Kong (HK1261581), protecting masitinib until 2037.

Based on the same rationale, medical use patents have been filed for treating progressive forms of multiple sclerosis, Alzheimer's disease, and prostate cancer with masitinib, which if granted, would protect the use of masitinib in these indications until 2041 (multiple sclerosis and Alzheimer's disease) and 2042 (prostate cancer).

## **Reference**

[1] Lortholary O, Chandesris MO, Bulai Livideanu C, et al. Masitinib for treatment of severely symptomatic indolent systemic mastocytosis: a randomised, placebo-controlled, phase 3 study. *Lancet*. 2017;389(10069):612-620.

## **About Indolent Systemic Mastocytosis**

Indolent systemic mastocytosis (ISM) is a hematological disease characterized by an abnormal number and activation of mast cells in the bone marrow and other organs. The disease is characterized by multiple symptoms that are disabling and can in some cases be life-threatening. Symptoms associated with ISM are predominantly associated with neurological disorders (depression, fatigue, cognitive impairment, headache), skin disorders (pruritus, skin lesions), flushing and gastro-intestinal disorders. ISM affects approximately 40,000 people in Europe and 25,000 in the USA. There is currently a high unmet medical need in this population.

## **About masitinib**

Masitinib is an 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 is 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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