



## PRESS RELEASE

### AB SCIENCE RECEIVES JAPANESE PATENT PROTECTION FOR THE USE OF MASITINIB IN PROGRESSIVE FORMS OF MULTIPLE SCLEROSIS (MS) UNTIL 2041

THIS IS THE FIRST COUNTRY DELIVERING THE MS PATENT

MASITINIB HAS UNIQUE AND COMPETITIVE POSITIONING IN PROGRESSIVE FORMS OF MULTIPLE SCLEROSIS DUE TO ITS DISTINCTIVE SAFETY AND EFFICACY PROFILE AND MECHANISM OF ACTIONS TARGETING BOTH MICROGLIA AND MAST CELLS

*Paris, January 21, 2026, 6pm CET*

**AB Science SA** (Euronext - FR0010557264 - AB) today announced that the Japanese Patent Office has formally granted a patent for methods of treating progressive multiple sclerosis (MS) with its lead compound masitinib. This new patent (JP 7788154) ensures intellectual property protection for masitinib until February 2041.

This is the first country to deliver the patent to protect the use of masitinib in progressive forms of MS.

AB Science has followed for the protection of masitinib in progressive forms of MS the same methodology as for the use of masitinib in ALS. This last patent was granted everywhere in the world.

AB Science is optimistic in its chance to receive the protection of the use of masitinib in progressive MS worldwide.

The same secondary medical use patent strategy is pursued for several indications, including amyotrophic lateral sclerosis until 2037 (with 5 years possible extension), progressive forms of MS and Alzheimer's Disease until 2041, sickle cell disease until 2040, and prostate cancer until 2042, severe mastocytosis until 2036.

Masitinib unique and competitive positioning in progressive forms of MS, both primary progressive multiple sclerosis (PPMS) and non-active secondary progressive multiple sclerosis (nSPMS)

Masitinib is positioned as a treatment of progressive MS patients, including the subvariants of PPMS and nSPMS.

- **The development of masitinib in progressive forms of multiple sclerosis is based on the positive phase 2b/3 study (AB07002) and confirmatory phase 3 MAXIMS study (AB20009)**

Study AB07002 (656 enrolled patients) achieved its primary analysis endpoint, showing a statistically significant reduction in the cumulative change in EDSS with masitinib 4.5 mg/kg/day ( $p=0.0256$ ) [1]. This treatment effect was consistent for both PPMS and nSPMS. Masitinib significantly reduced the risk of first disability progression by 42% and improved manual dexterity, as measured by the 9-hole peg test ( $p=0.0388$ ). Furthermore, the risk of reaching an Expanded Disability Status Scale (EDSS) score of 7.0, indicating a level of disability severe enough to confine the patient to a wheelchair, was significantly reduced ( $p=0.0093$ ). Masitinib's safety was consistent with the known risk profile of masitinib, with no increased risk of infection.

Study AB20009 (MAXIMS) is a randomized, double-blind, phase 3 study of masitinib 4.5 mg/kg/day in patients with PPMS and nSPMS. The objective of this study is to confirm the positive results of study AB07002. Study

AB20009 will enroll patients with an EDSS score of 3.0-6.0, disease progression within 2 years of randomization, and the absence of T1 Gadolinium-enhancing brain lesions. The primary endpoint of this study is the effect of masitinib on the time to confirmed disability progression over 96 weeks, with progression defined as a 1-point worsening when the EDSS baseline score is  $\leq 5.5$  or a 0.5-point worsening if the EDSS baseline score is  $> 5.5$ .

- **Masitinib safety profile is based on a large database**

The safety profile of masitinib is well characterized based on a safety population of more than 4,300 patients, including close to 2,000 patients receiving masitinib for more than 6 months and 1,200 patients receiving masitinib for more than a year.

Interestingly, masitinib does not target B-cells, unlike BTK inhibitors, another class of tyrosine kinase inhibitors developed for multiple sclerosis. Targeting B cells, which are not a therapeutic target in progressive forms of multiple sclerosis, is associated with an increased risk of infection and immunological changes.

Safety population		Patients exposed to Masitinib				
	All	$\leq 3$ months	More than 3 months	More than 6 months	More than 1 year	More than 2 years
All	4,318	1,674	2,644	1,924	1,255	560
Healthy volunteers	96	96	0	0	0	0
Non-oncology subjects	2,184	565	1,619	1,307	958	453
Oncology subjects	2,038	1,013	1,025	617	297	107
<i>ICH Topic E1 requirements for non-orphan drugs</i>	1,500			300-600	100	

- **Masitinib is the first in class and only drug in phase 3 designed to specifically target both mast cells and microglia, with strong evidence that this dual targeting the innate immune system is an effective strategy for the treatment of progressive forms of multiple sclerosis**

Masitinib is a first-in-class oral tyrosine kinase inhibitor, capable of slowing functional decline in progressive MS by selectively targeting the innate immune system through both mast cells and microglia, and without any apparent negative impact on B-cell or T-cell activity.

Masitinib has demonstrated the ability to decrease serum neurofilament light chain (NfL) concentration in an animal model of MS, and by extension, possibly neuronal damage [2].

Masitinib targets microglia and mast cells, both of which play crucial roles in progressive MS and the experimental autoimmune encephalomyelitis (EAE) model of MS, as evidenced by numerous publications [3-13].

- **There is a strong medical need for the progressive forms of multiple sclerosis**

Multiple Sclerosis is an autoimmune disease of the central nervous system that affects more than 100,000 people in France and for which no definitive treatment exists to date. It is characterized by progressive degradation of the nerve cells of the central nervous system by the patient's immune system and comes in two main forms.

**The relapsing-remitting form (RRMS)** is characterized by relapses of the disease. During these relapses, patients experience the onset of new symptoms or worsening of existing symptoms. These flare-ups are usually followed by recovery periods of varying lengths, after which some symptoms may persist.

Relapsing-remitting forms of multiple sclerosis are mostly associated with dysfunction of adaptive immunity<sup>1</sup> (B and T cells).

**The progressive form** (PPMS and nSPMS) is characterized by a constant and regular worsening of the symptoms of the disease without a distinct relapse or period of recovery. The rate of onset of severe, disabling, and irreversible disability is much higher in the progressive forms of the disease than in the relapsing-remitting forms. In progressive multiple sclerosis, innate<sup>2</sup> immune cells, such as macrophages, microglia, and mast cells, play a major role.

To date, the vast majority of treatments for the management of multiple sclerosis target the patient's adaptive immune system and, therefore, mainly apply to relapsing-remitting forms of the disease. However, patients with progressive forms of the disease currently account for approximately 50% of MS cases.

The medical need in PPMS remains very high, following mixed results from BTK inhibitors in multiple sclerosis. Tolebrutinib (Sanofi) failed in phase 3 studies in RRMS and PPMS, while showing a positive result in nSPMS that nonetheless resulted in an FDA Complete Response Letter due to significant safety concerns, including a high risk of fatal drug-induced liver injury. Evobrutinib (Merck/EMD Serono) and fenebrutinib (Roche/Genentech) failed to demonstrate efficacy in RRMS Phase 3 trials, with fenebrutinib showing only non-inferiority to ocrelizumab in PPMS. Consequently, evobrutinib development was discontinued. Remibrutinib (Novartis) is the only BTK inhibitor with ongoing phase 3 trials in RRMS.

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<sup>1</sup> Adaptive immunity corresponds to the immune protection that an individual builds over the course of his or her life according to the pathogens to which his or her organism is exposed.

<sup>2</sup> An individual's innate immunity represents his immune protection from birth.

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#### **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)