



**AB SCIENCE ANNOUNCES THAT HEALTH CANADA HAS GRANTED AUTHORIZATION TO FILE A NEW DRUG SUBMISSION FOR MASITINIB IN THE TREATMENT OF AMYOTROPHIC LATERAL SCLEROSIS (ALS) UNDER THE NOTICE OF COMPLIANCE WITH CONDITIONS (NOC/c) POLICY**

**AB SCIENCE WILL HOST A WEBCAST TO PROVIDE DETAILS ON THIS APPLICATION AND AN UPDATE ON THE MASITINIB DEVELOPMENT PLAN**

*Paris, 21 February, 2022, 5.45pm CET*

**AB Science SA** (Euronext - FR0010557264 - AB) today announces that Health Canada has granted authorization to file a New Drug Submission for masitinib in the treatment of amyotrophic lateral sclerosis (ALS) under the Notice of Compliance with Conditions (NOC/c) policy.

Market authorization under the NOC/c policy allows Health Canada to provide earlier market access to potentially life-saving drugs. NOC/c status is given to eligible drugs that have demonstrated promising clinical effectiveness in clinical trials. The products must be of high quality and possess an acceptable benefit/risk profile. Eligibility is restricted to promising new drug therapies intended for the treatment, prevention or diagnosis of serious, life-threatening or severely debilitating diseases or conditions for which: a) there is no alternative therapy available on the Canadian market or, b) where the new product represents a significant improvement in the benefit/risk profile over existing products.

An assessment named Advance Consideration, performed by a Health Canada Adjudicating Committee, is necessary before being granted authorization to file under NOC/c policy.

This assessment was made based on a pre-submission package sent by AB Science including, efficacy data of study AB10015, long-term survival data (75 months average follow-up from diagnosis) of study AB10015, and safety data.

The Adjudicating Committee has concluded that the request does fulfill the criteria for filing and advance consideration under the NOC/c policy.

The following points were considered by this entity to deliver authorization to file under NOC/c:

- Masitinib is represented for the treatment, prevention or diagnosis of a serious, life-threatening or severely debilitating disease or condition, since ALS is a serious, life-threatening and severely debilitating disease, with a median survival of 2 years after diagnosis.
- There is promising evidence of clinical effectiveness that masitinib provides a significant increase in efficacy and/or significant decrease in risk such that the overall benefit/risk profile is improved over existing therapies, preventatives or diagnostic agents for a disease or condition that is not adequately managed by a drug marketed in Canada.

On this latter point, the Adjudicating Committee concluded that: The data presented provide promising evidence of the clinical effectiveness of masitinib 4.5 mg/kg/day in the preplanned study population, both in terms of slowing disease progression and in reducing mortality in patients with moderate ALS when compared to riluzole alone. Further, despite no head-to-head trial, masitinib with background riluzole therapy has shown a survival benefit that has not been demonstrated with edaravone therapy. Data also presented an acceptable high level assessment of the clinical safety profile in these patients who require

effective new therapies for this progressive, life-threatening medical condition. Therefore, there is an improvement in the overall benefit/risk over marketed ALS therapies in Canada.

If granted, an NOC/c is authorization to market a drug with conditions. Such conditions will be discussed with Health Canada during the procedure.

Under the NOC/c policy, AB Science has 60 calendar days to file its application and Health Canada has a target of 200 calendar days to review the application. AB Science intends to submit its marketing authorization application in less than 60 days.

An estimated 3,000 Canadians are currently living with ALS. Each year approximately 1,000 Canadians die from ALS. A similar number of Canadians are diagnosed with ALS each year.

Alain Moussy, co-founder and CEO of AB Science, said *“We welcome the decision of Health Canada to authorize filing of the masitinib registration dossier in ALS. We are committed to work with Health Canada on this new drug submission, which could potentially lead to the rapid availability of masitinib to ALS patients through the NOC/c policy and ultimately to full registration. We thank all investigators and researchers who have supported the masitinib development program in ALS over several years. Above all, we are very pleased with this decision for the ALS patients and community, for whom masitinib may offer a new therapeutic hope.”*

Professor Olivier Hermine, President of the Scientific Committee of AB Science and member of the Académie des Sciences in France said *“As a scientist and as the Director of the scientific strategy of AB Science, I am very happy with this news. Masitinib’s selective targeting of the innate immune system, predominately through modulation of mast cell and microglia activity, has proven to be the right strategy in neurodegenerative diseases and in particular for ALS. For me, it is the unique mechanism of action of masitinib that explains the efficacy observed at week 48 on the slowing of functional decline, as measured by the ALSFRS-R score [1], and the extended survival by a median of 25 months in patients who started treatment prior to severe impairment of functionality, ideally at the time of diagnosis, as was seen in the very long-term follow-up of 7 years [2].”*

AB Science will hold a webcast on Monday 28 February at 6 pm CET, where two topics will be discussed:

- Masitinib filing in the treatment of ALS in Canada under the NOC/c procedure
- Update of masitinib clinical program in all indications

#### **References**

- [1] Mora JS, Genge A, Chio A, et al. Amyotroph Lateral Scler Frontotemporal Degener. 2020;21(1-2):5-14.  
[2] Mora JS; Bradley WG; Chaverri D, et al. Ther Adv Neurol Disord 2021, Vol. 14: 1–16

#### **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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