



## PRESS RELEASE

### **AB SCIENCE ANNOUNCES THAT IT HAS RECEIVED A SECOND AUTHORIZATION TO RESUME PATIENT ENROLLMENT, IN THE PHASE 3 STUDY OF MASITINIB IN MASTOCYTOSIS**

*Paris, 25 august 2021, 6.45pm CET*

**AB Science SA** (Euronext - FR0010557264 - AB) announced today that it has received authorization from the French National Agency (ANSM) to resume patient enrollment in the confirmatory Phase 3 study of masitinib (AB15003) in mastocytosis.

This authorization follows the validation in July 2021 by the ANSM [1] of the measures proposed by AB Science to reinforce patient safety related to cardiac risk in its ongoing studies.

This authorization is the result of a constructive interaction with the French agency based on signal detection, which shows that the pharmacovigilance system in place is properly working.

This is the second clinical study for which patient enrollment has been authorized to resume, following the authorization received in amyotrophic lateral sclerosis [2].

AB Science expects to be able to progressively resume global patient enrollment in mastocytosis study during the month of September.

This temporary interruption does not modify the recruitment schedule, with recruitment completion expected in 2022 for this confirmatory study, as initially planned.

[1] Press release dated July 12, 2021

[2] Press release of August 23, 2021

#### **About studies AB15003 and AB06006**

As a reminder, study AB15003 is a multicenter, randomized, double blind, placebo-controlled, phase 3 study to compare the efficacy and safety of masitinib dose titration up to 6 mg/kg/day with that of placebo in treatment of patients with severe indolent systemic mastocytosis, unresponsive to optimal symptomatic treatment.

The study is designed to enroll 140 patients with or without the D816V mutation of c-Kit. The primary endpoint is a measure of the cumulative response on 3 severe symptoms of mast cell mediator release (pruritus, flush and depression) from week 8 to week 24.

This AB15003 study is intended to confirm the previously published results from the first Phase 3 study (AB06006), which demonstrated that masitinib can substantially reduce severe symptoms associated with indolent systemic mastocytosis, regardless of a patient's c-Kit mutational status. In this previous study, the superiority of masitinib was measured by the cumulative 75% response rate until week 24 on the handicaps of pruritus or flushes or depression or fatigue (4H75% response). The 4H75% response was 18.7% for the masitinib treatment-arm versus 7.4% for the placebo treatment-arm. Study results were published in *The Lancet*.

### **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 no therapy approved for the treatment of ISM.

### **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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