



PRESS RELEASE

AB SCIENCE HAS BEEN GRANTED AUTHORIZATION TO INITIATE PHASE II STUDY IN PATIENTS WITH SEVERE MAST CELL ACTIVATION SYNDROME BY THE FRENCH HEALTH AUTHORITY (ANSM)

Paris, 19 January, 2022, 6pm CET

AB Science SA (Euronext - FR0010557264 - AB) today announces that it has been authorized by the French Medicine Agency, ANSM, to initiate a Phase II study (AB20006) in patients with severe mast cell activation syndrome.

Study AB20006 is titled '*A 24-week, multicenter, randomized, double blind, placebo-controlled, dose-range finding phase 2 study to compare efficacy and safety of oral masitinib to placebo in treatment of patients with severe mast cell activation syndrome (MCAS) or severe smoldering or indolent systemic mastocytosis (SSM/ISM) with handicap unresponsive to optimal symptomatic treatment*'. The study will enroll 60 patients from numerous study centers. The treatment objective in severe MCAS is to reduce symptoms (pruritus, flush, depression) and improve impaired quality-of-life.

Study AB20006 has also been approved by the U.S. Food and Drug Administration (FDA).

Professor Olivier Hermine, President of the Scientific Committee of AB Science and member of the Académie des Sciences in France said, "*We are pleased to receive this ANSM approval to begin masitinib MCAS clinical trials in Europe, which when taken together with the previous FDA approval is a strong signal that masitinib has international KOL support in this indication. MCAS is a newly recognized disorder, distinct from but closely related to systemic mastocytosis and for which there is a far greater prevalence in the general population. Masitinib's proven ability to substantially reduced severe mast cell mediator release symptoms in mastocytosis, regardless of the patient's c-Kit mutational status [1,2], suggests that masitinib is particularly well-suited for the treatment of severe MCAS, for which there are currently no registered therapeutic drugs.*"

MCAS is a disease caused by inappropriate activation of mast cells, which can lead to mast cell mediator release symptoms with a severity ranging from mild to life-threatening. In this aspect, MCAS is similar to indolent and smoldering systemic mastocytosis (ISM/SSM), however, important differences exist that make MCAS a distinct entity from systemic mastocytosis. In mastocytosis, well-defined mutations result in an aberrant population of mast cells with a marked increased proliferation in tissues, whereas MCAS is driven by greater (ill-defined) mutational heterogeneity that is associated with aberrant mast cell activation but only modest increases in mast cell numbers due to reduced apoptosis [3]. Another striking difference between systemic mastocytosis and MCAS is the prevalence of these diseases. Systemic mastocytosis is considered to be a rare, orphan disease affecting about 1/100,000 people, whereas MCAS has an estimated prevalence of 1–17% of the population (i.e., at least a 1000-fold difference) [4,5].

Because masitinib has been designed to be a potent inhibitor of mast cell activation (through its action against wild-type c-Kit, Lyn and Fyn tyrosine kinases), it is uniquely well-suited for the treatment of severe MCAS, unlike other c-Kit tyrosine kinase inhibitors that typically target specific c-Kit mutations that are associated with systemic mastocytosis. There are currently no approved therapies for severe MCAS or drugs in clinical development for this indication.

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.

[2] Paul C, Sans B, Suarez F, et al. Masitinib for the treatment of systemic and cutaneous mastocytosis with handicap: a phase 2a study. *Am J Hematol*. 2010;85:921–25.

[3] Afrin LB, Ackerley MB, Bluestein LS, et al. Diagnosis of mast cell activation syndrome: a global "consensus-2". *Diagnosis (Berl)*. 2020;8(2):137-152. Published 2020 Apr 22.

[4] Molderings GJ, Haenisch B, Bogdanow M, Fimmers R, Nöthen MM. Familial Occurrence of Systemic Mast Cell Activation Disease. *PLoS One*. 2013;8:e76241.

[5] Haenisch B, Nöthen MM, Molderings GJ. Systemic mast cell activation disease: the role of molecular genetic alterations in pathogenesis, heritability and diagnostics. *Immunol*. 2012; 137:197–205.

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.

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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