PRESS RELEASE

AB SCIENCE RECEIVES U.S. FOOD AND DRUG ADMINISTRATION (FDA) AUTHORIZATION TO START CLINICAL DEVELOPMENT PROGRAM OF MASITINIB IN MAST CELL ACTIVATION SYNDROME (MCAS)

MCAS IS A NEWLY RECOGNIZED DISORDER, DISTINCT FROM BUT CLOSELY RELATED TO SYSTEMIC MASTOCYTOSIS AND FOR WHICH THERE IS A FAR GREATER PREVELANCE IN THE GENERAL POPULATION

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AB Science SA (Euronext - FR0010557264 - AB) today announced that its clinical development program of masitinib in adult patients with mast cell activation syndrome (MCAS) has been approved by the U.S. Food and Drug Administration (FDA). The Investigational New Drug (IND) approval letter received from the FDA provides authority to proceed with 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.

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 [1]. 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) [2,3].

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.

Professor Mariana Castells (Professor of Medicine at Harvard Medical School and the Director of the Brigham and Women's Hospital Mastocytosis Center, Boston, USA) said, "*We are very excited about the news of FDA approval to begin masitinib clinical trials in mast cell activation syndromes. Masitinib represents a path forward for severe MCAS patients, for whom there is a significant unmet medical need and no clinical trials*".

Dr Lawrence Afrin (AIM Center for Personalized Medicine, USA) a leading expert in MCAS said, "*MCAS is frequently unrecognized and misdiagnosed because symptoms associated with it are often present in other medical conditions and are highly variable among patients. Nevertheless, it is now apparent that*

mastocytosis, a malignancy of the mast cell, comprises only a very small proportion of the overall burden of mast cell activation disease, with a far larger bulk of this population consisting of MCAS patients. Given the comparatively large number of MCAS patients suffering severe symptoms, the development of a targeted drug such as masitinib in this indication is of enormous importance."

Professor Olivier Hermine, President of the Scientific Committee of AB Science and member of the Académie des Sciences in France said, "*Based on our extensive knowledge of masitinib's mechanism of action in mast cell disease and clinical experience of treating indolent systemic mastocytosis, we believe that masitinib is particularly well-suited for the treatment of severe MCAS, for which there are currently no registered therapeutic drugs. Indeed, masitinib has already shown potential efficacy in a population that closely matches the targeted population of severe MCAS having substantially reduced severe mast cell mediator release symptoms in mastocytosis, regardless of the patient's c-Kit mutational status [4,5].*"

Reference

[1] 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.

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

[3] 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.

[4] 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.

[5] 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.

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 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.

For additional information, please contact:

AB Science
Financial Communication & Media Relations
investors@ab-science.com

Media Relations – USA
RooneyPartners
Kate Barrette
kbarrette@rooneypartners.com
+1 212 223 0561

Media Relations – France
NewCap
Arthur Rouillé
arouille@newcap.fr
+33 (0)1 44 71 00 15