

# Results from masitinib study AB07015 in severe asthma selected for presentation at an American Thoracic Society (ATS) symposium held on 16<sup>th</sup> October, 2020

**AB Science SA** (Euronext - FR0010557264 - AB) today announced that results from masitinib study AB07015 in severe asthma have been selected for presentation at an upcoming American Thoracic Society (ATS) symposium.

The ATS Allergy, Immunology, and Inflammation Assembly will host a virtual symposium on October 16, 2020 at 10 am (Eastern Standard Time). This is a chaired virtual meeting during which selected abstracts from the ATS 2020 International Conference (ATS 2020 Virtual) are presented live with questions from moderators and audience.

Pascal Chanez, Professor of Respiratory Diseases at Aix-Marseille University, France, will present the results of masitinib as a treatment of severe corticosteroid-dependent asthma.

Details for the presentation are as follows:

Session Title: Late Breaking Clinical Trials in Airway Diseases

Date and time: Friday, October 16<sup>th</sup> at 10 am (Eastern Standard Time)

Presentation Title: Masitinib Significantly Decreases the Rate of Asthma Exacerbations in Patients with

Severe Asthma Uncontrolled by Oral Corticosteroids: A Phase 3 Multicenter Study

## Registration details are shown below:

https://thoracic.zoom.us/meeting/register/tJEvceyrqTIjGNXFa7z-dd2tA-gxuumtkd5H

The full abstract [1] has been published in the American Journal of Respiratory and Critical Care Medicine, 2020 Volume 201. https://www.atsjournals.org/doi/book/10.1164/ajrccm-conference.2020.B93.

ATS is one of the world's largest meetings for pulmonary medicine professionals and has been historically well-attended by key opinion leaders and decision-makers in asthma research and healthcare policy. Due to the current COVID-19 pandemic, the 2020 ATS International Conference in Philadelphia, USA was cancelled with select elements of the conference content now provided as a virtual format.

Pascal Chanez said: "Selection of this abstract for live webcast as part of the ATS virtual symposium on Clinical Trials in Airway Diseases, is an indication of masitinib's potential impact on the treatment landscape in severe asthma".

Olivier Hermine (President of the Scientific Committee of AB Science and member of the Académie des Sciences in France) said: "There is a strong rationale to develop masitinib in severe asthma with research implicating mast cells and PDFGR signaling as being crucial factors for initiating, promoting and sustaining pathophysiological processes that drive asthma exacerbations and structural changes of the airway in severe asthmatics [2–6]. Moreover, increased mast cell activity is associated with both eosinophilic (Th2-high) and non-eosinophilic (Th2-low) asthma" [7].

# Study AB07015 highlights

Masitinib is a *first in class* oral drug in severe asthma, selectively targeting mast cells through inhibition of tyrosine kinases c-Kit, LYN and FYN. There is a strong scientific rationale to target mast cells in asthma and

study AB07015 was the first positive large-scale study in severe asthma utilizing a drug that targets mast cells. Additionally, masitinib is a potent inhibitor of Platelet-Derived Growth Factor Receptor (PDGFR), which is associated with airway remodeling in asthma. Masitinib is therefore capable of simultaneously modulating independent mechanisms of asthma pathophysiology, which is an attractive therapeutic strategy for severe asthma.

Phase 3 study (AB07105) evaluating oral masitinib at 6 mg/kg/day versus placebo in severe asthma uncontrolled by oral corticosteroids (OCS) met its primary endpoint. Masitinib significantly decreased the rate of severe asthma exacerbations in patients with severe asthma uncontrolled by OCS, regardless of baseline eosinophil level.

Study AB07015 demonstrated efficacy in a difficult to treat population:

- Primary analysis was conducted in the severe asthma population with daily OCS ≥ 7.5 mg and masitinib treatment was associated with a significant reduction in severe asthma exacerbations (-35%, p=0.0103).
- A pre-specified subgroup of severe asthma patients with high eosinophil counts (≥ 150 cells/μL) also demonstrated a statistically significant reduction in rate of severe asthma exacerbations (-38%, p=0.0156).
- Benefit of masitinib was greatest in patients who had higher cumulated use of OCS (indicative of more severe asthma that is harder to control) with statistically significant reduction in rate of severe asthma exacerbations of up to -71% for patients with high eosinophil counts (≥ 150 cells/µL) receiving an annualized cumulative OCS intake of >1000 mg.

Study AB07015 population is distinct from other asthma trials:

- Patients dependent on OCS (100% receiving high dose OCS therapy) and no weaning
- Patients were treated irrespective of baseline eosinophil count
- Evaluated over a long period of time (approx. 13 months)

Masitinib has a unique positioning in severe asthma, in terms of administration (oral administration), mechanism of action, targeted population, and broad eosinophil level.

- 1) P. Chanez, E. Israel, L. Davidescu, et al. American Journal of Respiratory and Critical Care Medicine. https://doi.org/10.1164/ajrccm-conference.2020.201.1\_MeetingAbstracts.A4210
- 2) Penn RB. Mast cells in asthma: Here I am, stuck in the middle with you. Eur Respir J2020; 56: 2001337
- 3) Kardas G, Daszyńska-Kardas A, Marynowski M, Brząkalska O, Kuna P, Panek M. Role of Platelet-Derived Growth Factor (PDGF) in Asthma as an Immunoregulatory Factor Mediating Airway Remodeling and Possible Pharmacological Target. Front Pharmacol. 2020;11:47.
- 4) Bradding P, Arthur G. Mast cells in asthma—state of the art. Clin Exp Allergy. 2016;46(2):194-263.
- 5) Balzar S, Fajt ML, Comhair SA, et al. Mast cell phenotype, location, and activation in severe asthma. Data from the Severe Asthma Research Program. Am J Respir Crit Care Med. 2011;183(3):299-309.
- 6) Carter RJ, Bradding P. The role of mast cells in the structural alterations of the airways as a potential mechanism in the pathogenesis of severe asthma. Curr Pharm Des. 2011;17(7):685-698.
- 7) Maun HR, Jackman JK, Choy DF, et al. An Allosteric Anti-tryptase Antibody for the Treatment of Mast Cell-Mediated Severe Asthma Cell. 2019;179(2):417-431.e19.

### **About masitinib**

Masitinib is a new 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.

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, and inflammatory 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 filed by AB Science with the Autorité des Marchés Financiers (AMF), including those listed in the Chapter 4 "Risk Factors" of AB Science reference document filed with the AMF on November 22, 2016, under the number R. 16-078. 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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