



**AB SCIENCE ANNOUNCES PUBLICATION IN THE *JOURNAL OF ASTHMA AND ALLERGY* OF POSITIVE MASITINIB PHASE 3 CLINICAL TRIAL RESULTS IN PATIENTS WITH ORAL CORTICOSTEROID-DEPENDENT SEVERE ASTHMA**

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**AB Science SA** (Euronext - FR0010557264 - AB) today announced publication of results from its positive study of masitinib in severe asthma uncontrolled by oral corticosteroids (OCS) in the peer-reviewed *Journal of Asthma and Allergy* [1].

This article, titled 'Efficacy and Safety of Masitinib in Corticosteroid-Dependent Severe Asthma: A Randomized Controlled Trial' is freely accessible online from the journal website:

<https://www.dovepress.com/getfile.php?fileID=81290>

Lavinia Davidescu, MD, Professor of Pulmonology at the University of Oradea, Romania, and coordinating investigator of study AB07015, said: *"Unlike other drugs for severe asthma, masitinib innovatively targets the dual mechanisms of mast cell-related asthma pathophysiology and PDGFR-related airway remodeling. Results from this phase 3 study showed that corticosteroid-dependent severe asthma patients treated with masitinib at 6.0 mg/kg/d had a lower risk of severe asthma exacerbations compared with those in a placebo-control group that did not receive masitinib. Benefit of masitinib was also shown to be greatest in the most severely affected patients, that is to say, those who required a higher cumulative oral corticosteroid dose. Safety results from this study were consistent with the known profile for masitinib, with no new safety concerns, indicating that masitinib may provide a new effective treatment option for oral corticosteroid-dependent severe asthma, including severe asthmatics that are ineligible to receive or in failure to registered biologics."*

Pascal Chanez, MD, Professor of Respiratory Diseases at Aix-Marseille University, France, and senior author of this article commented: *"Because mast cells are increasingly recognized as being involved in pathophysiological processes that drive exacerbations and structural changes of the airway in severe asthmatics, possibly through modulation of steroid insensitive pathways [2–8], there is a strong rationale to use masitinib, a selective mast cell inhibitor, as an adjunct therapy in corticosteroid-dependent severe asthma. Results from this study show that oral masitinib has achieved the main therapeutic objectives for a drug in severe asthma, both in terms of significant reduction in the rate of severe exacerbations and improved pulmonary function, and notably does so through an entirely different mechanism to that which is associated with Type-2 targeted biologics."*

**Study AB07015 highlights**

Phase 3 study (AB07105) evaluating oral masitinib at 6 mg/kg/d 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.

Study AB07015 demonstrated efficacy in a difficult to treat population:

- Primary analysis was conducted in the severe asthma population with daily OCS  $\geq 7.5$  mg and masitinib treatment was associated with a significant reduction in severe asthma exacerbations of 35%,  $p=0.0103$  (annualized rate adjusted for the overall time on treatment).

- A pre-specified subgroup of severe asthma patients with high eosinophil counts ( $\geq 150$  cells/ $\mu\text{L}$ ) also demonstrated a statistically significant reduction in rate of severe asthma exacerbations of 38%,  $p=0.0156$  (annualized rate adjusted for the overall time on treatment).
- 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 ( $\geq 150$  cells/ $\mu\text{L}$ ) receiving an annualized cumulative OCS intake of  $>1000$  mg.
- Additional sensitivity analysis using the ERS/ATS task force recommended definition of severe exacerbations for clinical trials (i.e., an increase in stable maintenance dose of OCS for at least 3 days, wherein said increase was defined as a dose of at least 40 mg/day), showed that masitinib consistently and significantly reduced rate of severe asthma exacerbations relative to placebo across all time points tested (overall time on treatment, weeks 36, 48, 52, 72, and 96).

Study AB07015 population was distinct from other asthma trials:

- Patients were dependent on OCS (100% receiving high dose OCS therapy) and no weaning
- Patients in the primary analysis population 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 broader eosinophil level.

## References

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2. Penn RB. Mast cells in asthma: here I am, stuck in the middle with you. *Eur Respir J*. 2020;56(1):2001337.
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8. 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 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

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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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