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AB Science to present results from its Phase 3 AB07015 study in severe asthma at the annual European Respiratory Society International Congress

# Abstract selected for moderated ALERT session (Abstracts Leading to Evolution in Respiratory Medicine Trials) held on 8<sup>th</sup> September, 2020

**AB Science SA** (Euronext - FR0010557264 - AB) today announced that an abstract reporting results from its Phase 3 AB07015 study on severe asthma uncontrolled by oral corticosteroids, has been selected for an 'ALERT' oral presentation at the 30<sup>th</sup> annual European Respiratory Society (ERS) International Congress (September 07-09, 2020). The ALERT session is intended to showcase important clinical trial data from the most ground-breaking randomized clinical trial (RCT) submissions.

Pascal Chanez, Professor of Respiratory Diseases at Aix-Marseille University, France, will present key data from the positive Phase 3 study (AB07015) as part of the meeting's ALERT session (Abstracts Leading to Evolution in Respiratory Medicine Trials). This is a moderated session during which a few select abstracts are presented live and then discussed by session chairs/moderators and the audience.

Details for the live ALERT presentation are as follows:

Presentation Title:	Masitinib in severe asthma: Results from a randomized, phase 3 trial
Session Title:	Session: ALERT: Asthma in adults and children
Date and time:	Tuesday - 8 September at 14:30-15:30 (CEST)

This ALERT abstract will also be presented in the e-poster format on the congress platform and the abstract will be published in a supplement (September 2020 edition) of the European Respiratory Journal.

The annual European Respiratory Society (ERS) International Congress is the largest meeting in the respiratory field, which in previous years has welcomed over 20,000 delegates from around the world, and is renowned as a showcase of excellence across the entire field of respiratory medicine. The 30<sup>th</sup> anniversary of the ERS Congress will be an innovative and interactive virtual event.

Pascal Chanez said: "Selection of this abstract for an ALERT oral presentation at the ERS 2020 Congress is an indication of the clinical relevance of study AB07015 and masitinib's potential impact on the treatment landscape for severe asthma".

Olivier Hermine (President of the Scientific Committee of AB Science and member of the Académie des Sciences in France) said: *"Biologics for severe asthma are typically only effective in patients with a high eosinophil count of greater than 300 cells/µL. In contrast, masitinib is effective across a broad population, regardless of the eosinophil level, and may therefore provide a new treatment option for biologic-ineligible patients or patients in failure to biologics".* 

## 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 targeting mast cells [1]. Additionally, masitinib is a potent inhibitor of Platelet-Derived Growth Factor Receptor (PDGFR), which is associated with airway remodeling in asthma [2]. 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. 60 weeks)

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

[1] Bradding P, Arthur G. Clin Exp Allergy. 2016 Feb;46(2):194-263.

[2] Kardas G, et al. Front Pharmacol. 2020 Feb 14;11:47.

### 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.

### 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, 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: <u>www.ab-science.com</u>.

### 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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