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## Summary of webcast with Key Opinion Leaders on masitinib Phase 3 results in severe asthma uncontrolled by oral corticosteroids

**AB Science SA** (NYSE Euronext - FR0010557264 - AB) is providing a summary of the live webcast held on 02 December with key opinion leaders on severe asthma uncontrolled by oral corticosteroids (OCS) and the role that masitinib may play in treating this disorder.

The presentation of the webcast is available on the company's website.

A replay of the webcast is available at the following address: [Webcast Replay](#)

### Experts' opinion

Masitinib is a *first in class* oral drug in severe asthma, selectively targeting mast cells. 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.

Study AB07015 demonstrated efficacy in a difficult to treat population, with 100% of patients receiving high dose (OCS) maintenance therapy, but not required to have high blood eosinophil levels. Results demonstrating masitinib's reduction of severe asthma exacerbations were consistent and robust.

- The pre-specified 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. This positive primary analysis detected a 35% statistically significant reduction ( $p=0.0103$ ) in severe exacerbation rate between masitinib and placebo. The study also demonstrated a significant treatment effect in the Intent-To-Treat (ITT) population, which included (non-severe) patients with OCS < 7.5 mg (-33%,  $p=0.0156$ ).
- There was a center effect, with greater efficacy noted in the EU countries (-51% reduction in severe asthma exacerbations,  $p=0.0038$ ).
- The pre-specified analysis in the population of patients with severe asthma with high eosinophil counts ( $\geq$  150 cells/ $\mu$ L) also demonstrated a statistically significant reduction in rate of severe asthma exacerbations (-38%,  $p=0.0156$ ).

The clinical data are encouraging and we are optimistic about the future development of masitinib in severe asthma.

- There was a significant reduction in rate of severe asthma exacerbations in difficult to treat severe asthma patients that required OCS maintenance treatment.
- In the patients enrolled in European Union countries, the 51% reduction in rate of severe asthma exacerbations was comparable to other studies with biologics.

The masitinib safety profile was acceptable based on available data. The occurrence of adverse events (AEs) and serious adverse events (SAEs) was comparable between masitinib and placebo.

Masitinib is uniquely positioned in severe asthma with respect to administration (oral administration), mechanism of action, an identified target population, concomitant use of OCS, and eosinophil counts in the studied population.

There is still a need for alternative therapies in asthma despite the progress achieved in recent years. Masitinib has several strategic positioning opportunities in severe asthma that are complementary to biologics utilization. Masitinib could potentially be positioned in the following indications:

- Severe asthma insufficiently controlled by biologics, as a single agent or in combination (i.e. after biologics).
- Severe asthma in Non-Type 2 inflammatory phenotypes (i.e. in first line treatment of low eosinophilic patients with eosinophil count  $\leq 300$  or  $\leq 150$  cells/ $\mu\text{L}$ ).
- Severe asthma in the “vulnerable” zone of biologics (i.e. in first line treatment of patients with eosinophil count  $\geq 150$  and  $\leq 300$  cells/ $\mu\text{L}$ ).

## **KOL Biography**

The following key opinion leaders participated in the webcast:

**Pascal CHANEZ, MD, PhD:** Dr. Pascal Chanez is Professor of Respiratory Medicine at the APHM and Aix Marseille University at Marseille France. He coordinates a research group at INSERM-CNRS - Aix Marseille University CV2N Center on the role of bronchial epithelium in inflammation and environmental aggression in severe bronchial diseases. He is the head of a clinical research group investigating new innovative treatments for severe asthma and COPD. He is the author or co-author of more than 300 peer reviewed articles, reviews and monographs. He was an editor of the European Respiratory Journal and is an editor of the Journal of allergy and clinical Immunology. His clinical and research interests are devoted to a better understanding of the mechanisms of severe asthma and COPD with a special focus on combining clinical and biological findings to identify new specific biomarkers and therapies.

**Lavinia DAVIDESCU, MD, PhD:** Dr. Lavinia Davidescu is Assistant Professor at the Faculty of Medicine and Pharmacy, University of Oradea. She is president of the Rare Disease Section of Romanian Pneumology Society, member in the boarding Committee of the Romanian Society of Pneumology. She is the coordinating investigator of masitinib study AB07015 in severe asthma uncontrolled with oral corticosteroids.

**Elliot ISRAEL, MD:** Dr. Elliot Israel is the director of clinical research in the Pulmonary and Critical Care Medicine Division and an associate physician at Brigham and Women’s Hospital (BWH). He is also a professor of medicine at Harvard Medical School. Dr. Israel’s research interests include therapeutic interventions to alter asthmatic airway hyperactivity and the role of arachidonic acid metabolites in airway narrowing. He has written over 200 peer-reviewed publications and currently leads a team researching novel asthma treatments funded by the National Institutes of Health. He is the recipient of the HMS Daniel D. Federman Outstanding Clinical Educator Award and was named one of “Boston’s best in Pulmonary Medicine” by Boston Magazine.

## **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: [www.ab-science.com](http://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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#### **AB Science**

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