



## PRESS RELEASE

### **AB SCIENCE ANNOUNCES THAT IT HAS RECEIVED AUTHORIZATION TO RESUME PATIENT ENROLLMENT IN ITS PHASE 2 COVID-19 STUDY OF MASITINIB, SIGNIFYING RESUMPTION OF RECRUITMENT IN ALL THREE OF ITS ONGOING MASITINIB STUDIES**

*Paris, 16 September 2021, 7.30pm CET*

**AB Science SA** (Euronext - FR0010557264 - AB) announced today that it has received authorization from the Russian Health Ministry (MoH) to resume patient enrollment in the phase 2 masitinib study of COVID-19 (AB20001).

This latest authorization signifies that the measures proposed by AB Science to reinforce patient safety related to cardiac risk are adequate for all three of its ongoing masitinib studies.

Authorizations to resume patient enrollment have already been received from European and National agencies [1] [2] for the confirmatory Phase 3 study (AB19001) in amyotrophic lateral sclerosis and the confirmatory Phase 3 study (AB15003) in mastocytosis.

Study AB20001 is a randomized (1:1), double-blind, Phase 2 clinical trial to evaluate the safety and efficacy of masitinib combined with isoquercetin in hospitalized patients with moderate and severe COVID-19. Many patients with moderate and severe COVID-19 develop a “cytokine storm” that leads to severe pulmonary inflammation and various thrombotic events associated with acute respiratory distress syndrome and potentially death. The combination of masitinib and isoquercetin may prevent the development of these two complications. Study AB20001 plans to enroll 200 patients (age  $\geq 18$  without an upper age limit) with a primary objective to improve the clinical status of patients after 15 days of treatment.

The Data and Safety Monitoring Board (DSMB) have met twice since the beginning of the study and have recommended continuation of the study on both occasions.

Of major relevance to the development of masitinib in COVID-19 is the recent publication of research article in the journal *Science* that demonstrated the effectiveness of masitinib as an anti-SARS-CoV-2 drug in animals [3]. Mice infected with SARS-CoV-2 and then treated with masitinib showed >200-fold reduction in viral titers in the lungs and nose, as well as improved overall lung pathology and significantly reduced levels of key pro-inflammatory cytokines. Overall, results showed that masitinib rapidly and effectively reduced SARS-CoV-2 viral load in mice (reducing >99% of the viral load on day 6), reduced inflammatory signatures, and showed potential benefits for survival and clinical scores. Remarkably, masitinib was also effective, *in vitro*, against all tested variants of concern, including the rapidly spreading Alpha, Beta and Gamma variants.

[1] Press release dated September 14, 2021

[2] Press releases of August 23, 2021 and August 25, 2021

[3] Drayman N, DeMarco JK, Jones KA, et al. Masitinib is a broad coronavirus 3CL inhibitor that effectively blocks replication of SARS-CoV-2. *Science*. 2021;373(6553). doi: 10.1126/science.abg5827

#### **About masitinib**

Masitinib is a 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](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 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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