



PRESS RELEASE

AB SCIENCE RECEIVES REGULATORY AUTHORIZATION TO COMMENCE A SECOND PHASE 2 COVID STUDY

STUDY DESIGN FOCUSES DIRECTLY ON MASITINIB'S ANTIVIRAL ACTIVITY AGAINST THE COVID-19 VIRUS (SARS-CoV-2) FOR THE TREATMENT OF PATIENTS AT AN EARLY STAGE OF THE DISEASE

WITH TWO PHASE 2 STUDIES, MASITINIB IS A LEADING CANDIDATE IN THE DEVELOPMENT OF ORAL PROTEASE INHIBITORS FOR TREATMENT OF NON-HOSPITALIZED AND HOSPITALIZED COVID-19 PATIENTS

Paris, 28 September, 2021, 7pm CET

AB Science SA (Euronext - FR0010557264 - AB) today announced that a new clinical trial with masitinib in patients with symptomatic mild and moderate COVID-19 has been approved by the Regulatory Authorities of Russia and South Africa. Study AB21002, the second Phase 2 study of masitinib in COVID-19, is titled '*A randomized, double-blind, placebo-controlled, phase 2 clinical trial to evaluate the antiviral efficacy of masitinib in patients with symptomatic mild to moderate COVID-19*'.

Masitinib is being developed as a novel SARS-CoV-2 protease inhibitor antiviral therapy, with two phase 2 studies in the complementary populations of non-hospitalized (non-severe) and hospitalized (severe) COVID-19 patients. Masitinib is considered particularly well-suited for the treatment of COVID-19 soon after infection (prior to hospitalization), when an antiviral is likely to have most effect and because of its convenient oral (tablet) administration. Currently, masitinib is one of the most advanced oral protease inhibitor antiviral drugs in clinical development, as its safety is well-known, having already been evaluated on thousands of patients in other indications.

Study AB21002 will evaluate the antiviral efficacy of masitinib at 3 different dosages, administered as an add-on to best supportive care, with respect to placebo plus best supportive care. The study will enroll 78 patients (age ≥ 18 without an upper age limit) at medical centers in France and other countries. The primary efficacy objective will be to demonstrate that masitinib can reduce the viral load of SARS-CoV-2 (the virus responsible for COVID-19) faster than a placebo control group, which will receive best supportive care. The population of study AB21002 therefore targets ambulatory (non-hospitalized) patients with mild disease or hospitalized patients without requirement for non-invasive ventilation (a score of 4 and 5 on the WHO clinical progression scale for COVID-19).

This clinical trial follows the discovery published in the journal *Science* [1] that masitinib is a direct antiviral drug blocking the replication of SARS-CoV-2 (the virus that causes COVID-19), by inhibiting the critical non-structural protein 5 (Nsp5) target (the main protease also named 3CLpro) necessary for the viral replication cycle. In a mice model infected with SARS-CoV-2, masitinib was shown to dramatically reduce the viral load, the pro-inflammatory cytokines levels, and to improve mice survival at clinically relevant dosages. Masitinib therefore has a dual action against COVID-19; a direct antiviral mechanism of action and also an anti-inflammatory action that is of relevance for treating COVID-19 related acute respiratory distress syndrome and cytokine storm.

Professor Savas Tay, senior author of the *Science* article [1] (Pritzker School for Molecular Engineering, University of Chicago) previously commented that, "*In a context where we face the emergence of a number of SARS-CoV-2 variants of concern, the development of efficacious antiviral therapeutics is urgently needed.*"

Because masitinib specifically targets the catalytic residues of 3CLpro, its antiviral activity is likely to be insensitive to genetic alterations of the Spike protein. Thus, masitinib constitutes a uniquely valuable therapeutic option for both ancestral SARS-CoV-2 and variants against which vaccines or monoclonal antibodies may become less or not effective” [2].

Despite the availability of effective vaccines, the need for antiviral therapeutics will remain high because a substantial part of the world population will not be vaccinated. In addition, SARS-CoV-2 is rapidly evolving, leading to the selection and accumulation of mutations, mainly in the Spike protein, that affect the transmissibility of the virus, its ability to evade immunity and its suspected pathogenicity. Variants of concern are more contagious and susceptible of immune escape, thereby challenging monoclonal antibodies (mAbs) therapies, threatening the protective efficacy of current vaccines and leading to waves of coronaviruses.

At this time, there is a lack of antiviral compounds available to treat COVID-19. Consequently, there is an urgent need to develop new antiviral compounds in order to counter emerging variants of concerns.

The development of effective antiviral therapies is based on two complementary strategies:

- Drugs targeting the polymerase: Several drugs targeting polymerase are currently in clinical development, with remdesivir (Gilead) being approved.
- Drugs targeting the protease: Drugs targeting viral 3C-like protease (as is the case for masitinib) are an attractive therapeutic option for COVID-19, in part because they are considered less vulnerable to the development of SARS-CoV-2 drug resistance; however, no such drugs targeting 3C-like protease are yet registered for use in the treatment of COVID-19.

As is the case to treat HIV (human immunodeficiency virus), it is expected that an effective treatment strategy against SARS-CoV-2 would depend on the combination of drugs targeting both the polymerase and the protease of the virus.

Reference

[1] 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

[2] Press release dated April 6, 2021. www.ab-science.com/signing-of-an-exclusive-licensing-agreement-with-the-university-of-chicago-to-conduct-research-for-the-prevention-and-treatment-of-covid-19/

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.

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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