Press release

Biophytis Receives Approval from the French Health Authority (ANSM) to Initiate COVA, a Clinical Trial with Sarconeos (BIO101) for the Treatment of COVID-19 Related Respiratory Failure

Phase 2/3 clinical trial expected to start in France in the coming weeks

Paris, (France), Cambridge (Massachusetts, United States), July 27th, 2020, 8:00 a.m. CEST - Biophytis SA (Euronext Growth Paris: ALBPS), a clinical-stage biotechnology company specialized in the development of drug candidates for treatment of aged related diseases, amongst which neuromuscular diseases, today announces that it has received approval from the French National Agency for the Safety of Medicines and Health Products (ANSM) to proceed with its clinical development program: COVA. The program will assess Sarconeos (BIO101) as a potential treatment for acute respiratory failure associated with COVID-19. Biophytis has already received similar approval from FAMHP (Belgium), the MHRA (UK) and US FDA.

The COVA clinical program is designed to evaluate the efficacy and the safety of Sarconeos (BIO101) as a treatment to prevent further respiratory deterioration in COVID-19 patients with severe respiratory failure. A Phase 2/3, randomized, double-blind, placebo-controlled, adaptive and seamless study assessing Sarconeos (BIO101) in patients infected with SARS-CoV-2 is expected to start in the coming weeks in France.

This potentially pivotal, international clinical trial is a two-stage study that will be coordinated by Dr. Capucine Morelot-Panzini, Professor of Pulmonology at the Pitié-Salpêtrière University Hospital in Paris and Principal Investigator of COVA in France.

The first part of the study will recruit COVID-19 patients who have developed severe respiratory symptoms within the last 7 days. This first part will include 50 COVID-19 patients and the second part an addition of 260 COVID-19 patients. The total number of patients included in the study should therefore be around 310 patients.

The primary endpoint is the proportion of all-cause mortality and respiratory deterioration within up to a 28-day period.

Secondary endpoints include improvements in the patients' respiratory function, and the effect on biomarkers associated with the mechanism of action of Sarconeos (BIO101). The potential benefits of the products (on the Renin Angiotensin System, muscle tissues and inflammatory markers) will also be evaluated.

The COVA study is an adaptive study with 2 planned interim analyses that will be conducted by an independent data-monitoring committee (DMC).

The first interim analysis will be conducted when the first 50 participants finish the study-intervention period. Upon the 'green light' to proceed, delivered by the DMC based on safety data, the Company can then continue recruiting into the second part. This analysis can also provide an initial proof of activity of Sarconeos (BIO101) on the study participants.

The second interim analysis will be conducted half way of the second part and will assess the final size of the cohort, estimated at this stage to 310 patients.

Stanislas Veillet, President and CEO of Biophytis, said: "*I am very pleased that after all of the hard work carried out by our teams over the past few months, we have received the approval from the ANSM to start our COVA clinical program. The study is to start in France mostly with the La Pitié-Salpêtrière Hospital, which is linked with Sorbonne University's medical school, a long-standing partner of Biophytis. This authorization comes at a crucial moment of COVID-19 upsurge in France and in Europe, re-emphazing the emergency of finding innovative treatments against the pandemics.*

Sarconeos (BIO101) has already demonstrated a good safety profile in the SARA clinical program to treat sarcopenia. The first part of the COVA study, which has already started in Belgium, the UK, and the USA, will provide us with important preliminary data as we work to confirm that Sarconeos (BIO101) can successfully prevent the deterioration of the respiratory function in Covid-19 patients. Based on its mode of action we are confident that Sarconeos (BIO101) could become an important - potentially life-saving - treatment for patients with acute respiratory failure associated with COVID-19. "

The Coronavirus SARS-CoV-2 can cause **A**cute **R**espiratory **D**istress **S**yndrome (ARDS) by disrupting the renin angiotensin system (RAS), which has a key role in regulating respiratory function. It is believed that SARS-CoV-2 enters the lung cells using the Angiotensin 2 Converting Enzyme (ACE-2), a key enzyme in the RAS, therefore inhibiting the system's protective arm.

Sarconeos (BIO101) activates the MAS receptor, a key component of the protective arm of the RAS, and has been shown to restore respiratory function in several preclinical models.

Sarconeos (BIO101) has demonstrated a good safety profile during the SARA development program, which is evaluating its ability to improve muscle function in frail elderly patients with sarcopenia. Sarconeos (BIO101) is also being developed to improve the respiratory function of children with Duchenne muscular dystrophy (DMD).

The COVA program builds on the clinical and preclinical data generated with Sarconeos (BIO101) in these neuromuscular diseases.

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About BIOPHYTIS

Biophytis SA is a clinical-stage biotechnology company specialized in the development of drug candidates to slow down degenerative processes and improve functional abilities in patients with age-related diseases, including neuromuscular diseases.

Sarconeos (BIO101), our leading drug candidate, is a small molecule, administered orally, currently in clinical Phase 2b in sarcopenia (SARA-INT) in the United States and Europe. A pediatric formulation of Sarconeos (BIO101) is being developed for the treatment of Duchenne Muscular Dystrophy (DMD). The company plans to start the clinical development (MYODA) in H2 2020.

Sarconeos (BIO101) is also being developed as a treatment for COVID-19. The Company has received approval from ANSM (France), FAMHP (Belgium), the MHRA (UK) and US FDA to begin the Phase 2/3 clinical trial (COVA) to evaluate Sarconeos (BIO101) as a potential treatment for respiratory failure associated with Covid-19.

The company is based in Paris, France, and Cambridge, Massachusetts. The company's common shares are listed on the Euronext Growth Paris market (Ticker: ALBPS -ISIN: FR0012816825). For more information visit www.biophytis.com

Disclaimer

This press release contains forward-looking statements. While the Company considers its projections to be based on reasonable assumptions, these forward-looking statements may be called into question by a number of hazards and uncertainties, so that actual results may differ materially from those anticipated in such forward-looking statements. For a description of the risks and uncertainties likely to affect the results, BIOPHYTIS' financial position, performance or achievements and thus cause a change from the forward-looking statements, please refer to the "Risk Factors" section of the Company's 2018 Annual Report available on BIOPHYTIS website (www.biophytis.com).

This press release, and the information contained in it, does not constitute an offer to sell or subscribe, nor the solicitation of a purchase or subscription order, of BIOPHYTIS shares in any country. The elements contained in this communication may contain forward-looking information involving risks and uncertainties. The Company's actual achievements may differ materially from those anticipated in this information due to different risk and uncertainty factors. This press release was written in French and English; If there is a difference between the texts, the French version will prevail.

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