

Biophytis Enrolls First Patient in Brazil in COVA, a Multinational Phase 2/3 Clinical Trial with Sarconeos (BIO101) for the Treatment of Patients with COVID-19 Related Respiratory Failure

First Patient Dosed at Hospital e Maternidade Celso Pierro - PUCCAMP in Campinas

Ten centers now open for patient recruitment in Europe and the Americas

Paris, (France), Cambridge (Massachusetts, United States), October 26, 2020, 8:00 a.m. CET - Biophytis SA (Euronext Growth Paris: ALBPS), a clinical-stage biotechnology company specialized in the development of drug candidates for treatment of age-related diseases, including neuromuscular diseases, today announces that the first patient in Brazil has been dosed at Hospital e Maternidade Celso Pierro - PUCCAMP in Campinas in COVA, a Phase 2/3 Clinical Trial with Sarconeos (BIO101) for the treatment of patients with COVID-19-related respiratory failure. The multinational trial is progressing at pace with ten centres now open to recruit patients in Belgium, France, Brazil and in the US.

Ludhmila Abrahão Hajjar, MD, PhD, Professor at the Faculty of Medicine University of São Paulo, (InCor HCFMUSP, São Paulo, Brazil) and Principal Investigator of COVA in Brazil, said: *“There is currently an urgent need for improved treatment options to help COVID-19 patients, and particularly those in vulnerable categories who are most at risk of suffering severe respiratory complications. Having dosed the first patient with BIO101 here in Brazil, we are hoping that our clinical research will help find an urgently needed treatment option that could improve the care of vulnerable COVID-19 patients globally.”*

The COVA clinical program (clinicaltrials.gov identifier *NCT04472728*) is a Phase 2/3, randomized, double-blind, placebo-controlled, adaptive and group sequential study assessing Sarconeos (BIO101) in patients aged 45 and older, infected with SARS-CoV-2. It is designed to evaluate the efficacy and the safety of Sarconeos (BIO101) as a treatment to prevent further deterioration in patients with COVID-19-related respiratory failure. The objective is to prevent them from being admitted to the intensive care unit (ICU) and requiring ventilation.

This pivotal multinational clinical trial is being conducted in two parts, the first of which will assess the treatment safety and provide an indication of activity of Sarconeos (BIO101) in 50 hospitalized COVID-19 patients suffering from acute respiratory deficiency.



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The second part of the study will investigate the efficacy of Sarconeos (BIO101) on the respiratory function of an additional 260 COVID-19 patients.

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

Secondary endpoints include records of improvement, worsening and hospital discharge, functional scales and the biomarkers associated with the mechanism of action of Sarconeos (BIO101) and inflammation.

Stanislas Veillet, CEO of Biophytis says: *“We are delighted to have started dosing the first patient in Brazil, a country particularly hard-hit by the pandemic. Biophytis is one of the few European biotechs with access to a strong network of clinic sites in the Americas, especially Latin America where we have recently reactivated our Brazilian branch. This milestone highlights the excellent progress we are making in evaluating BIO101 as a potentially improved and differentiated treatment option for patients with COVID-19 related severe respiratory manifestations globally.”*

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 patients with COVID-19 related respiratory failure in a Phase 2/3 clinical study (COVA) in the United States, Europe and Latin America.

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

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