

Biophytis - First Patient Enrolled in France in COVA, an International Phase 2/3 Clinical Trial with Sarconeos (BIO101) for the Treatment of COVID-19 Related Respiratory Failure

First Patient Dosed at La Pitié-Salpêtrière University Hospital in Paris

Total of eight centers authorized by French National Health Agency (ANSM) for patient recruitment in France

Paris, (France), Cambridge (Massachusetts, United States), December 11, 2020, 8:00 a.m. CET - Biophytis SA (Euronext Growth Paris: ALBPS), a clinical-stage biotechnology company focused on the development of therapeutics that slow the degenerative processes associated with aging and improve functional outcomes for patients suffering from age-related diseases, including severe respiratory failure in patients suffering from COVID-19, today announces that the first French patient has been dosed at La Pitié-Salpêtrière University Hospital, Paris, in COVA. The COVA study is a Phase 2/3 clinical trial with Sarconeos (BIO101) for the treatment of patients with COVID-19-related respiratory failure. Dr. Capucine Morelot-Panzini, Professor of Pulmonology at the Pitié-Salpêtrière University Hospital in Paris is the Principal Investigator of COVA in France.

In addition to the two first centers at the Pitié-Salpêtrière University Hospital in Paris, Biophytis also received approval from the French National Agency for Medicines and Health Products Safety (ANSM) this month to open six new centers in France, among which *Centre Hospitalier Rene Dubos* and *Centre Hospitalier d'Argenteuil* in the Paris Region, bringing the total to eight centers planned to recruit COVID-19 patients in France.

A total of 17 centers are now actively recruiting in Belgium, Brazil, France and the US among a targeted number of around thirty to be opened for the second part of the COVA study .

The international COVA clinical program (clinicaltrials.gov identifier *NCT04472728*) is a global, multicentric, double-blind, placebo-controlled, group-sequential and adaptive two-part Phase 2-3 study assessing Sarconeos (BIO101) in patients aged 45 and older, infected with SARS-CoV-2.

This pivotal 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 patients. The study is designed to evaluate the efficacy and the safety of Sarconeos (BIO101) as a treatment to prevent further deterioration of patients with COVID-19-related respiratory failure, which could otherwise require admission to the intensive care units and ventilation.



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The first part of the study is a Phase 2 exploratory proof of concept study to provide preliminary data on the activity, safety and tolerability of Sarconeos (BIO101) in 50 hospitalized patients with severe respiratory manifestations related to COVID-19.

The second part of the study will investigate the safety and efficacy of Sarconeos (BIO101) on the respiratory function of 310 COVID-19 patients (including the 50 patients from Part 1 of the study).

Interim analysis and completion of full trial enrollment is expected in Q1 2021.

Stanislas Veillet, CEO of Biophytis says: *"I am very pleased that after all of the efforts by our teams over the past few months, we can now announce the first patient has been dosed at La Pitié-Salpêtrière Hospital and start our COVA clinical program in France. We have been working for many years with the team at La Pitié-Salpêtrière Hospital, which is linked with Sorbonne University's medical school, a long-standing partner of Biophytis. The continued surge of COVID-19 cases in France, Europe and the Americas and subsequent hospitalizations, re-emphasizes the emergency of finding innovative treatments against the pandemic (even while a vaccine is being rolled-out).*

We project enrollment of the 50 patients required for the first part of the study to complete in the coming weeks. Topline results of the COVA trial are expected in Q2 2021."

About BIOPHYTIS

Biophytis SA is a clinical-stage biotechnology company specialized in the development of therapeutics that slow the degenerative processes associated with aging and improve functional outcomes for patients suffering from age-related diseases, including severe respiratory failure in patients suffering from COVID-19.

Sarconeos (BIO101), our leading drug candidate, is a small molecule, administered orally, being developed as a treatment for sarcopenia in a Phase 2 clinical trial in the United States and Europe (SARA-INT). It is also being studied in a clinical two-part Phase 2/3 study (COVA) for the treatment of severe respiratory manifestations of COVID-19 in Europe, Latin America and the US.

A pediatric formulation of Sarconeos (BIO101) is being developed for the treatment of Duchenne Muscular Dystrophy (DMD).

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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