

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

First Patient Dosed at Natchitoches Regional Medical Center in Louisiana - US

Total of seven centers open for patient recruitment in Europe and the Americas

Paris, (France), Cambridge (Massachusetts, United States), October 13, 2020, 7:00 p.m. CEST - 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 US patient has been enrolled in the COVA study at Natchitoches Regional Medical Center, Barnum Medical Research, in Louisiana (US).

Biophytis holds an Investigational New Drug (IND) application from the FDA to start COVA, a multinational Phase 2/3 Clinical Trial with Sarconeos (BIO101) for the treatment of patients with COVID-19-related respiratory failure, in the US.

The trial has been making good progress with now seven centers open and ready to recruit COVID-19 patients in Belgium, France, Brazil and in the US.

Dr Otis Barnum, MD, internist in Natchitoches, Louisiana and Principal Investigator Coordinator of COVA in US, said: *“Finding an effective therapeutic agent to treat patients who became severely ill due to COVID-19 is vital if we are going to reduce the mortality rate and hospitalization from this pandemic. The objective of this study is to investigate whether BIO101 can prevent further respiratory deterioration, reduce mortality and the duration of hospitalization in these patients.”*

The COVA clinical study (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 55 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.



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This pivotal multinational clinical trial will be 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.

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: *“At Biophytis we are working hard to rapidly recruit the patients needed, to help determine whether Sarconeos (BIO101) has the potential to play a role in addressing the COVID-19 global pandemic. The COVA trial will provide important clinical data to determine the potential benefit that Sarconeos (BIO101) can deliver via its activity on the renin angiotensin system (RAS), which plays a key role in regulating respiratory functions.*

We project enrollment of the 50 patients required for the first part of the study to complete before the end of the year, provided the opening of 20 centers in the study. The results of the COVA trial are expected before the end of 2021, depending on the evolution of the pandemic.”

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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Biophytis Contact for Investor Relations

Evelyne Nguyen, CFO

evelyne.nguyen@biophytis.com

Media contact

Citigate Dewe Rogerson

Sylvie Berrebi/ Nathaniel Dahan/ David Dible / Quentin Dussart

biophytis@citigatedewerogerson.com

Tel: +44 (0) 20 7638 9571 / +33 (0)1 55 30 70 91