Press release

Biophytis Enrolls First Patient 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 in Mechelen, Belgium

5 centers in Belgium, France and the US are open for patient recruitment

Paris, (France), Cambridge (Massachusetts, United States), September 1, 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 age-related diseases, including neuromuscular diseases, today announces that the first patient has been dosed at AZ Sint Maarten hospital in Mechelen, Belgium 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 has been making good progress and now has five centers ready for patients recruitment in Belgium, France and the US.

Dr Muriel Lins, Pulmonologist at AZ Sint Maarten hospital in Mechelen and Principal Investigator Coordinator **of COVA in Belgium**, said: "*COVID-19 can have devastating effects on patients, particularly those in vulnerable categories, who are at risk of developing severe respiratory complications, and there is much need for more treatment options to address those. We are pleased to be the first site to treat patients with BIO101. It reflects on our commitment to advancing clinical research on COVID-19 to provide patients with severe respiratory manifestations the best care and improve their chances of survival*."

The COVA clinical program is a Phase 2/3, randomized, double-blind, placebo-controlled, adaptive and group sequential study assessing Sarconeos (BIO101) in patients infected with SARS-CoV-2. It 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.

This pivotal clinical trial (NCT04472728) taking place in Belgium, France, Brazil, the UK and US, will be conducted in two parts, the first of which has the objective to assess 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 trial expects to recruit a total of about 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 records of improvement, worsening and hospital discharge, functional scales and the biomarkers associated with the mechanism of action of Sarconeos (BIO101) and inflammation.

"*The Coronavirus SARS-CoV-2 can cause Acute Respiratory Distress Syndrome (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 cells in various tissues using the Angiotensin 2 Converting Enzyme (ACE-2), a key enzyme in the RAS, thus inhibiting the system's protective arm. Sarconeos (BIO101) activates the MAS receptor, a key component of the protective arm of the RAS,"* added Dr Sam Agus, Chief Medical Officer of Biophytis. "*We believe that a drug with Sarconeos (BIO101)'s mode of action could provide an important treatment option for COVID-19 patients with severe respiratory failure*."

Stanislas Veillet, CEO of Biophytis says*: " Whilst in many countries COVID-19 has continued its steady spread, in Europe we are seeing again a worrying increase of new COVID-19 cases. With physicians still in need of effective treatments for COVID-19-related respiratory failure, we believe Sarconeos (BIO101) has the potential to serve as a differentiated treatment option for patients with severe respiratory manifestations. Our teams, together with SGS, a global CRO we selected, have been very active in implementing the protocol's requirements. The first patient dosed is an important milestone for the multinational COVA study which is now recruiting at five centers in France, Belgium and the US*."

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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 initiated the COVA trial in Belgium and also received approval from ANSM (France), ANVISA (Brazil), 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

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