**Press release**

# Biophytis Receives Approval from the Belgian Regulatory Agency (FAMHP) to Initiate COVA, a Clinical Trial with Sarconeos (BIO101) for the Treatment of Patients with COVID-19 Related Respiratory Failure

## *This Phase 2/3 clinical trial is expected to start in Belgium in the coming weeks*

**Paris, (France), Cambridge (Massachusetts, United States),** May 20, 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 Belgian regulatory agency, the Federal Agency for Medicines and Health Products (FAMHP), to proceed with its clinical development program COVA. This program will assess Sarconeos (BIO101) as a potential treatment for acute respiratory failure associated with COVID-19.

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 group sequential study assessing Sarconeos (BIO101) in patients infected with SARS-CoV-2 is expected to start in the coming weeks in Belgium.

Coordinated by Dr Muriel Lins, Pulmonologist at AZ Sint Maarten hospital in Mechelen and Principal Investigator of COVA in Belgium, this potential pivotal clinical trial will be a two-part study.

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 with the main criteria being the absence of patients with, high-flow oxygen use, assisted ventilation, or death, within a 28-day period. Multiple secondary criteria, including Sarconeos (BIO101)'s safety and tolerability, improvements in COVID-19 patients' respiratory function, and effects on biomarkers associated with the Renin-Angiotensin System (RAS), target of Sarconeos (BIO101) will also be evaluated.

An interim analysis conducted by an independent Data Monitoring Committee (DMC), expected in the 4$^{th}$ quarter of this year, subject to the evolution of the COVID-19 epidemic, will determine whether the study should progress into the second part and will allow recruitment of required sample size needed for detecting Sarconeos (BIO101) effects in part 2.

The interim analysis will also provide preliminary data on the efficacy of Sarconeos (BIO101) to prevent the deterioration of respiratory function in COVID-19 patients.

The second part of the COVA trial which will include at least 180 COVID-19 patients will also last 28 days and evaluate the same main and secondary criteria as those measured in the first part.

Stanislas Veillet, President and CEO of Biophytis, said: "*We are very pleased to have received approval from the FAMHP to start our COVA clinical program. We expect to start this important program in the coming weeks in Belgium as we look to extend to multiple sites in Europe and US pending potential approvals from the ANSM, MHRA and FDA. The first part of the COVA study 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 Company has also worked with its suppliers to ensure that it has access to sufficient Sarconeos (BIO101) to complete the multi-center COVA trial program as planned.

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 the lung cells using the Angiotensin 2 Converting Enzyme (ACE-2), a key enzyme in the RAS, 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, especially 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.

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Sarconeos (BIO101) will also be developed as a treatment for Covid-19 (Coronavirus). The Company has received approval from the Belgian Regulatory Authority (FAMHP) to begin the Phase 2/3 clinical trial (COVA) with Sarconeos (BIO101), evaluating it as a potential treatment for respiratory failure associated with Covid-19. The Company also filed clinical trial applications with the FDA in the US, MHRA in the UK and the French regulatory agency, ANSM in France.

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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