

## Biophytis Receives Approval from Brazilian Health Regulatory Agency to Start COVA, a Phase 2/3 Clinical Trial with Sarconeos (BIO101) for the Treatment of Patients with COVID-19 Related Respiratory Failure

Paris, (France), Cambridge (Massachusetts, United States), August 04, 2020, 8:00am CEST - Biophytis SA (Euronext Growth Paris: ALBPS), a clinical-stage biotechnology company specialized in the development of drug candidates for the treatment of aged related diseases, including neuromuscular diseases, today announces that it has received approval from the Brazilian Health Regulatory Agency, ANVISA (*Agencia Nacional de Vigilancia Sanitaria*), to start its clinical development program COVA in Brazil, where the Coronavirus SARS-CoV-2 is still very active with high transmission rates of the virus.

The COVA Phase 2/3 clinical program is designed to evaluate the efficacy and safety of Sarconeos (BIO101) as a treatment of the respiratory deterioration in COVID-19 patients with a respiratory failure.

This pivotal, international clinical trial (COVA NCT04472728) 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 total number of patients included in the study should therefore be around 310 patients.

Ludhmila Abrahão Hajjar, MD, PhD, Professor at the Faculty of Medicine University of São Paulo, (InCor HCFMUSP, São Paulo, Brazil), is COVA's Principal Investigator and National Coordinator in Brazil. Prof. Hajjar is a globally renowned cardiologist with extensive experience in the developments of intensive care medicines.

**Stanislas Veillet, CEO of Biophytis**, said: *"We are committed to providing an effective therapeutic option to help patients with COVID-19 Acute Respiratory Distress Syndrome (ARDS). The Americas are the new epicentre of the coronavirus pandemic with Brazil currently experiencing high rates of transmission of the disease. Extending our clinical trials to this country is a critical step in recruiting patients for this important study. We have reactivated our subsidiary in Brazil, which will play a key role in the timely execution of COVA in the interest of vulnerable populations, such as the elderly and those with comorbidities that are at highest risk of dying from SARS-CoV-2 globally."*

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## Press release

### 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 received approval from ANSM (France), FAMHP (Belgium), ANVISA (Brazil), the MHRA (UK) and the FDA in the US 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](http://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](http://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.

### Biophytis Contact for Investor Relations

Evelyne Nguyen, CFO

[evelyne.nguyen@biophytis.com](mailto:evelyne.nguyen@biophytis.com)

### Media contact

**Citigate Dewe Rogerson**

Sylvie Berrebi/ Nathaniel Dahan/ David Dible / Quentin Dussart



**Press release**

[biophytis@citigatedewerogerson.com](mailto:biophytis@citigatedewerogerson.com)

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