

## Biophytis Receives FDA IND Clearance for 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), July 1, 2020, 9:00 pm 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 the United States (US) Food and Drug Administration (FDA) has accepted the Investigational New Drug (IND) application to proceed with its clinical development program COVA. This Phase 2/3 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 safety of Sarconeos (BIO101) as a treatment of the respiratory deterioration in COVID-19 patients with severe respiratory failure. This pivotal, international clinical trial 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 around 300 additional patients.

**Stanislas Veillet, CEO of Biophytis,** said: *“There is an urgent need for therapies to help patients with COVID-19 Acute Respiratory Distress Syndrome (ARDS) given the continuing rapid spread of SARS-CoV-2 and limited therapeutic options. With FDA clearance, we intend to initiate a clinical trial to evaluate Sarconeos (BIO101) in patients with acute respiratory failure associated with COVID-19. The elderly and those with comorbidities are at highest risk of death from SARS-CoV-2. We have already initiated the work to start this key Phase 2/3 trial as soon as possible in the US, and in the European countries where we received approval, and will update the market shortly on our planned timelines.”*

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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



## Press release

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 FAMHP (Belgium), 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 also filed a clinical trial application with 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](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.

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