

Biophytis Receives MHRA Approval to Initiate the COVA Clinical Trial in the UK with Sarconeos (BIO101) for the Treatment of Patients with COVID-19 Related Respiratory Failure

Paris, (France), Cambridge (Massachusetts, United States), June 11, 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, including neuromuscular diseases, today announces that it has received approval from the UK Medicines and Healthcare Products Regulatory Agency (MHRA) 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 safety of Sarconeos (BIO101) as a treatment of the respiratory deterioration in COVID-19 patients with severe respiratory failure. This 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 the UK, upon approval of the relevant ethics committees. This pivotal, international clinical trial will be conducted in two parts, the first of which has the objective to assess treatment safety in 50 hospitalized COVID-19 patients suffering from acute respiratory deficiency, and to estimate the number of patients to be recruited in the second part to detect a significant effect of Sarconeos (BIO101) on the respiratory function.

Stanislas Veillet, CEO of Biophytis, said: *“We are very pleased to have received approval from the MHRA to start COVA in the UK. 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. SARS-CoV-2 enters cells in various tissues, particularly pulmonary tissues, using as a receptor 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.*

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. “

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.



Press release

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 FAMHP (Belgium) and the MHRA (UK) 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 clinical trial applications with the FDA in the US, 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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