

Biophytis Completes Recruitment of SARA-INT Phase 2b Study, Evaluating the Efficacy of Sarconeos (BIO101) in the Treatment of Sarcopenia

Protocol adapted to allow patient follow-up to take place at home due to Covid-19

Paris, France, Cambridge (Massachusetts, United States), March 24, 2020, 7:00 p.m. CET - Biophytis SA (Euronext Growth Paris: ALBPS), a clinical-stage biotechnology company with a primary focus on the development of its lead drug candidate, Sarconeos (BIO101), for the treatment of neuromuscular diseases, today announces that it has completed enrollment of the 231 patients into its SARA-INT Phase 2b study.

The SARA-INT study is a multicentre double-blind, placebo-controlled, randomized interventional Phase 2b clinical trial evaluating the safety and efficacy of Sarconeos (BIO101) administered orally in two doses (175 mg bid and 350 mg bid) in patients with sarcopenia at risk of mobility disability. The primary endpoint is the gait-speed over the 400-meter walk test (400MWT), which represents a measure of the participant's mobility function.

Sarcopenia is an age-related degeneration of skeletal muscle, which is characterized by a loss of muscle mass, strength, function and mobility disability, and increased risk of adverse health events and potential death resulting from falls, fractures, and physical disability. There are currently no approved drug treatments for sarcopenia, which has become the focus of increased research aiming to improve diagnosis and treatment. Sarcopenia is highly prevalent in the elderly (over 65) with an estimated prevalence between 6 and 22 percent.

Due to Covid-19, Biophytis has adapted the protocol to allow patient follow-up to take place at home, instead of requiring them to go to the investigation centers, following the US Food and Drug Administration (FDA) guidance and the Data and Safety Monitoring Board (DSMB) recommendations for preserving patients' safety in ongoing clinical trials. The company will closely monitor the situation as it evolves and follow recommendations of national and local governmental health organizations.

Stanislas Veillet, President and CEO of Biophytis, said: « *We are delighted to have completed patient recruitment and reached this important milestone for Biophytis. It is yet another important step in our development Sarconeos (BIO101), the only drug candidate currently in an advanced stage of development in humans for sarcopenia. This is an age-related degeneration of skeletal muscle characterized by a loss of muscle mass and strength that is currently without any treatment. We thank all of the patients and the investigators who are participating in this trial.*

Following recent confinement rules in the US and in Europe due to Covid-19 both FDA & DSMB have updated their guidance for conducting clinical trials. In view of these changes we have modified our SARA-INT protocol to allow patients' follow up to take place at their home in the safest conditions and in order to achieve the study in the most timely manner."



Press release

About BIOPHYTIS

Biophytis SA is a clinically staged biotechnology company specializing in the development of drug candidates to slow down degenerative processes and improve functional abilities in patients with age-related diseases, particularly 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 BIO101 is being developed for the treatment of Duchenne myopathy (DMD) for which the company received IND status by the U.S. Food and Drug Administration (FDA) in December 2019.

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 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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