

Biophytis Receives Approval from the Belgian Regulatory Agency to Proceed with the MYODA Program for Clinical Development of Sarconeos (BIO101) in Patients with DMD

MYODA clinical protocol adjusted with Respiratory Function now being the primary endpoint

Paris (France), Cambridge (Massachusetts, U.S.), March 30, 2020, 8:00 a.m. CET - Biophytis SA (Euronext Growth Paris: ALBPS), a clinical-stage biotechnology company with a primary focus on the treatment of neuromuscular diseases, today announces that it received approval from the Belgian regulatory agency, Federal Agency for Medicines and Health Products (FAMHP), to proceed with its clinical investigation of Sarconeos (BIO101) in non-ambulatory patients with Duchenne Muscular Dystrophy (DMD). This follows the FAMHP completion of the safety review of the clinical trial application filed by Biophytis earlier this year.

Biophytis' planned MYODA clinical program is based on a 3-part, randomized, double blind, adaptive seamless Phase 1 to 3 clinical study, to evaluate the safety and efficacy of a pediatric formulation of Sarconeos (BIO101) in non-ambulatory patients with DMD and evidence of respiratory deterioration. FAMHP also cleared a protocol adjustment that changed respiratory function to the primary endpoint. This protocol has also been discussed with the US Food and Drug Administration (FDA). The MYODA program was previously going to use a composite score to evaluate the functional benefits that Sarconeos (BIO101) can deliver in this indication.

Stanislas Veillet, Chief Executive Officer, stated: *"We are very pleased to have received approval to proceed with the MYODA clinical program in Belgium. Following encouraging preclinical data, we believe Sarconeos (BIO101) has the potential to be a much-needed treatment for DMD patients, a devastating disease with limited treatment options currently available. Our MYODA clinical program incorporates a seamless trial design that aims to clearly demonstrate the functional, and specifically respiratory benefits that Sarconeos (BIO101) could deliver to this severe and underserved patient population."*

"Due to Covid-19, the FDA updated its guidance for conducting clinical trials. As of today, we are still planning on initiating the MYOADA clinical program in H2 2020. We intend to update the market if the timeline changes."

The investigational plan includes a separate clinical trial to evaluate the safety and efficacy of Sarconeos (BIO101) in ambulatory DMD patients at a later date.

The development of Sarconeos (BIO101) in DMD has received strong interest from patient associations, among which AFM Téléthon in France. In June 2019 Biophytis and AFM Téléthon entered a collaboration agreement for the development of Sarconeos (BIO101) in this indication.

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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). The company intends to start MYODA clinical program in H2 2020.

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.

Biophytis Contact for Investor Relations

Evelyne Nguyen, CFO

evelyne.nguyen@biophytis.com

Media contact

Citigate Dewe Rogerson

Sylvie Berrebi/ Nathaniel Dahan/ David Dible / Quentin Dussart

biophytis@citigatedewerogerson.com

Tel: +44 (0) 20 7638 9571 / +33 (0)6 59 42 29 35