

## **Biophytis Receives FDA Approval to Proceed with the MYODA Program for Clinical Development of Sarconeos (BIO101) in Patients with Duchenne Muscular Dystrophy (DMD)**

**Paris (France), Cambridge (Massachusetts, U.S.)**, December 16, 2019, 8:00 a.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 received the approval from the U.S. Food and Drug Administration (FDA), neurology division, that it can proceed with its clinical investigation of a pediatric formulation of Sarconeos (BIO101) in patients with Duchenne muscular dystrophy (DMD). This follows the FDA's completion of the safety review of the IND application (IND 140530) filed by Biophytis in November 2019.

**Samuel Agus, M.D., Chief Medical Officer** of Biophytis, said: *"We are very pleased to have received the message that we may proceed with the MYODA clinical program. 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."*

The MYODA clinical program is an adaptive seamless Phase 1 to 3 clinical study, utilizing a composite score as the primary endpoint to assess the safety and efficacy of a pediatric formulation of Sarconeos (BIO101) for both ambulatory and non-ambulatory patients with DMD.

**Stanislas Veillet, Chief Executive Officer** of Biophytis, said: *"This is a great milestone for Biophytis and outlines the dedication and hard work of our team. We are grateful for the detailed guidance we have received from the regulatory agencies in designing our MYODA clinical program."*

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### **About Biophytis**

Biophytis is a clinical-stage biotechnology company focused on developing therapeutics that slow the degenerative processes associated with aging and improve functional outcomes for patients suffering from age-related diseases, with a primary focus on neuromuscular diseases.

Biophytis' lead drug candidate, Sarconeos (BIO101), is an orally administered small molecule, which is currently in a Phase 2b clinical trial for sarcopenia (SARA-INT) in the US and Europe. Biophytis has developed a pediatric formulation of Sarconeos (BIO101) for the treatment of Duchenne muscular dystrophy (DMD), which is expected to start a Phase 2 clinical trial in 2020. Biophytis' preclinical drug candidate, Macuneos (BIO201), is an orally administered small molecule in development for the treatment of retinopathies, including dry age-related macular degeneration (AMD) and Stargardt disease. Biophytis is headquartered in Paris, France, and has offices in Cambridge, Massachusetts. The Company's ordinary shares are listed on Euronext



Growth Paris (Ticker: ALBPS - ISIN: FR0012816825). For more information please visit [www.biophytis.com](http://www.biophytis.com).

### **Disclaimer**

This press release contains certain forward-looking statements. Although the Company believes its expectations are based on reasonable assumptions, these forward-looking statements are subject to numerous risks and uncertainties, which could cause actual results to differ materially from those anticipated. For a discussion of risks and uncertainties which could cause the Company's actual results, financial condition, performance or achievements to differ from those contained in the forward looking statements, please refer to the Risk Factors ("Facteurs de Risque") section of the Listing Prospectus upon the admission of Company's shares for trading on the regulated market Euronext Growth of Euronext Paris filed with the AMF, which is available on the AMF website ([www.amf-france.org](http://www.amf-france.org)) or on Biophytis' website ([www.biophytis.com](http://www.biophytis.com)).

This press release and the information contained herein do not constitute an offer to sell or a solicitation of an offer to buy or subscribe to securities of Biophytis in any country. Existing and prospective investors are cautioned not to place undue reliance on these forward-looking statements and estimates, which speak only as of the date hereof. Other than as required by applicable law, Biophytis undertakes no obligation to update or revise the information contained in this press release. This press release has been prepared in both French and English. In the event of any differences between the two texts, the French language version shall prevail.

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