

# Biophytis Files IND Application with FDA for Sarconeos (BIO101) to Support Planned MYODA Clinical Program in Patients with DMD

Paris (France), Cambridge (Massachusetts, U.S.), November 15, 2019, 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, announces it has filed an Investigational New Drug (IND) Application with the US Food and Drug Administration (FDA), which if granted, would allow it to begin the MYODA clinical development program with Sarconeos (BIO101) in patients with Duchenne muscular dystrophy (DMD) in 2020. The Company plans to file similar clinical trial applications to the applicable regulatory agencies in Europe before the year end.

Biophytis' proposed MYODA clinical program is based on a seamless trial design from Phase 1 to 3 and a composite score 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,** stated: "This IND filing is another key milestone in Biophytis' strategy to maximize the clinical utility of Sarconeos (BIO101) in patients with neuromuscular disease. Based on the pre-clinical data we have generated, we believe that Sarconeos (BIO101) could become an important new treatment option for patients with DMD. Our MYODA clinical program incorporate a seamless trial design that aims to clearly demonstrate the functional, including respiratory, benefits that Sarconeos (BIO101) could deliver to this underserved patient population."

In June 2019, Biophytis and AMF-Telethon entered a collaboration agreement for the development of Sarconeos (BIO101) for the treatment of DMD.

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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 U.S. and Europe. A pediatric formulation of Sarconeos (BIO101) is being developed for the treatment of Duchenne muscular dystrophy (DMD). Biophytis expects to begin the MYODA clinical program in patients with DMD in 2020, subject to regulatory approval. 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.



### 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) or on Biophytis' website (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.

# **Biophytis Investor Relations Contact**

Daniel Schneiderman, CFO dan.schneiderman@biophytis.com

Tel: +1 (857) 220-9720

## French and International Media Contact

Citigate Dewe Rogerson Sylvie Berrebi / Nathaniel Dahan / David Dible/ Quentin Dussart biophytis@citigatedewerogerson.com

Tel: +44 (0)20 76389571 / +33 (0)1 55 30 70 91

Source: Biophytis