

# Biophytis SARA-INT Phase 2b study, evaluating the efficacy of Sarconeos (BIO101) in sarcopenia, has now achieved over 50% patient recruitment

Paris (France), Cambridge (Massachusetts, United States), January 27, 2020, 8 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 recruited over 50% of the patients needed to complete the SARA-INT Phase2b clinical trial. At present, more than 50 patients have received 6 months of treatment. Based on an independent Data Safety Monitoring Board (DSMB) review (conducted every quarter, 4 times so far), to-date, there are no signals to warrant concerns on safety or tolerability of Sarconeos (BIO101).

The SARA-INT study is a multicenter 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. The study anticipates recruiting a total of 334 patients.<sup>1</sup>

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.

Samuel Agus, Chief Medical Officer, declares: "We are encouraged that we are now recruiting rapidly into the SARA-INT study. Our inclusion criteria, based on the initial findings from the SARA-OBS study, are designed to select a population, which is at higher risk of mobility disability. It has been a challenge to find these patients but having implemented a number of initiatives to speed up recruitment we are experiencing a significant rampup. We are confident of completing patient recruitment into the SARA-INT study as planned. We are also encouraged by the fact that the benefit:risk profile of Sarconeos (BIO101), continues to be considered by the DSMB as favorable."

**Stanislas Veillet, Chief Executive Officer,** says: "I am pleased that we have reached this important milestone in the SARA-INT study. With a total of 172 patients recruited in 22 clinical sites in the U.S. and in Belgium, we are confident that Biophytis can achieve this clinical trial on time and generate significant value."

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## **About Biophytis**

Biophytis is a clinical-stage biotechnology company focused on developing therapeutics that slow the

<sup>&</sup>lt;sup>1</sup> A protocol amendment that includes a reduction of the sample size needed for the study has been submitted to the FDA and is pending approval, re Biophytis press release dated October 31<sup>st</sup>, 2019





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), for which the company was granted FDA IND approval in December 2019.

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.

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