

Biophytis – Last patient completes final visit in SARA-INT, a Phase 2 clinical trial evaluating the efficacy of Sarconeos (BIO101) in the treatment of sarcopenia

Paris (France), Cambridge (Massachusetts, United States), December 16th, 2020, 8:00 a.m. CET - Biophytis SA (Euronext Growth Paris: ALBPS), a clinical-stage biotechnology company developing therapeutics that slow the degenerative processes associated with aging and improve functional outcomes for patients suffering from age-related diseases, including severe respiratory failure in patients suffering from COVID-19, today announces that the last patient in the Phase 2 clinical trial, SARA-INT, has completed his final on-treatment visit.

The objective of the SARA-INT Phase 2 study is to evaluate the efficacy and safety of Sarconeos (BIO101) in a randomized placebo-controlled study in patients over 65 years suffering from sarcopenia and considered at high risk of mobility disability. The primary endpoint of SARA-INT is patients' mobility disability as measured by the gait-speed over the 400-meter walk test (400MWT).

The multicentre double-blind, interventional study recruited a total of 233 patients in 22 centers in Belgium and the US who were dosed orally at 175 mg b.i.d. and 350 mg b.i.d. with Sarconeos (BIO101) through a 26-week period. 196 of those patients have completed the trial despite the COVID-19 pandemic.

The recently announced SARA-OBS results demonstrated that the very stringent inclusion criteria being used in the Phase 2 SARA-INT trial with Sarconeos (BIO101) has selected patients at confirmed higher risk of mobility disability (see [press release](#) from Monday December 14th).

This rapid deterioration in the mobility criteria, as measured by the 400-meter walk test, allows the treatment effect of Sarconeos (BIO101) to be observed when compared to placebo, in a smaller trial population.

Biophytis expects to report top-line data from this SARA-INT, Phase 2 clinical trial, in Q2 2021.

Stanislas Veillet, CEO of Biophytis, said *"The completion of patient treatment in SARA-INT is an important milestone in the development of Sarconeos (BIO101) for the treatment of sarcopenia. We are encouraged by the number of patients with severe sarcopenia that have been selected and have completed the study, especially during the COVID-19 pandemic. Indeed, over the 233 enrolled patients, 196 fully completed the trial, which will enable us to generate a clear set of data to evaluate Sarconeos (BIO101). We are currently analyzing this data and look forward to sharing the topline results of our study in Q2 2021. The conclusion of this trial takes us one step closer to bringing Sarconeos (BIO101) to the market for a sizeable indication with currently no approved treatment options.*

"I would like to take this opportunity to thank the participating physicians and patients in this program, and to congratulate our team for addressing the needs of sarcopenia patients."

About Sarcopenia

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 and development aiming to improve diagnosis and treatment. Sarcopenia is highly prevalent in the elderly (over 65) with an estimated prevalence between six and 22 percent.

About BIOPHYTIS

Biophytis SA is a clinical-stage biotechnology company specialized in the development of therapeutics that slow the degenerative processes associated with aging and improve functional outcomes for patients suffering from age-related diseases, including severe respiratory failure in patients suffering from COVID-19.

Sarconeos (BIO101), our leading drug candidate, is a small molecule, administered orally, being developed as a treatment for sarcopenia in a Phase 2 clinical trial in the US and Europe (SARA-INT). It is also being studied in a clinical two-part Phase 2/3 study (COVA) for the treatment of severe respiratory manifestations of COVID-19 in Europe, Latin America and the US.

A pediatric formulation of Sarconeos (BIO101) is being developed for the treatment of Duchenne Muscular Dystrophy (DMD).

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 visit 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 Annual 2019 Report and the Company's Half Year 2020 Report available on BIOPHYTIS website (www.biophytis.com).

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