Press Release

Biophytis - Protocol Amendment of SARA-INT, a Phase 2b Clinical Trial of Sarconeos (BIO101) in Sarcopenia, Cleared by FDA and AFMPS

- *Following this clearance, SARA-INT trial to recruit 231 patients vs. 334 initially planned*
- *More than 80% of patients are now recruited - completion of patient recruitment expected in Q2 2020*
- *Interim analysis by the study's data safety and monitoring board (DSMB) expected in Q2 2020*

Paris (France), Cambridge (Massachusetts, U.S.), February 11, 2020, 08:00 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 its protocol amendment for the SARA-INT trial, a phase 2b clinical trial of Sarconeos (BIO101) in sarcopenia, has been cleared by the U.S. Food and Drug Administration (FDA) and the Belgian regulatory agency, *L'Agence fédérale des médicaments et des produits de santé* (AFMPS).

The protocol amendment as approved will allow reduce by 30% the number of patients to be recruited into the SARA-INT clinical trial from 334 to 231 patients. This reduction in patient numbers will not change the objectives, endpoints or statistical power of the SARA-INT clinical trial.

This reduction is based on a preliminary analysis of the SARA-OBS observational study population, which experienced a faster deterioration of mobility function as measured by the 400-meter walk test (400MWT), the primary endpoint in the ongoing SARA-INT Phase 2b clinical trial. This finding confirmed that the more stringent inclusion criteria in the SARA-INT trial will result in the selection of patients that are at a high risk for mobility disability.

With a faster deterioration in mobility, it is reasonable to expect, that if Sarconeos (BIO101) is beneficial for these patients, that a larger functional difference will be seen between the treated patients and those who received placebo.

The amendment includes an unblinded interim analysis by the study's data safety by the monitoring board (DSMB). The interim analysis will be based on a subset of 50 patients that have completed six months of treatment with Sarconeos (BIO101). The results of the interim analysis are expected in Q2 2020.

Stanislas Veillet, Chief Executive Officer of Biophytis, said, "*We are very pleased that the US and Belgium regulatory authorities have accepted our protocol amendment to the SARA-INT clinical trial. This is an important development as it enables us to significantly reduce the number of patients that we need to recruit into the study without altering its objectives, endpoints and statistical power. We now anticipate delivering topline results towards the end of 2020.*"

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Sam Agus, Chief Medical Officer of Biophytis, *said: "Recruitment into the study has been steadily accelerating across the trial's 20 centers in the US and 2 centers in Belgium, we are now at more than 80% of patient recruitment. As a result, we are confident of completing recruitment in Q2 2020*."

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 SARA-OBS results and its impact on the SARA-INT study were presented at the 12th Annual Congress of The Society on Sarcopenia, Cachexia and Wasting Disorders (SCWD) in Berlin (Germany) in a presentation entitled, *SARA program: Preliminary Findings & Implications from SARA-OBS Study and Its Impact on SARA-INT study*, on Saturday December 7, 2019.

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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), 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

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