Press Release

Biophytis Files Protocol Amendment to Optimize the SARA-INT Phase 2b Clinical Trial for Sarcopenia

- *The amendment, which was filed with the FDA and AFMPS, proposes a reduction in the number of patients needed in SARA-INT based on fast deterioration of mobility seen in the SARA-OBS study in participants with sarcopenia*
- *Interim analysis planned to assess the likelihood of success of the SARA-INT study based on the revised participant population size*

Paris (France), Cambridge (Massachusetts, U.S.), October 31, 2019, 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, announces the filing of an amendment to the SARA-INT Phase 2b clinical trial protocol with 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 amendment proposes a reduction in the target number participants that will need to be recruited into the SARA-INT study. This planned change is based on preliminary analysis of the SARA-OBS study population, presented at the European Geriatric Medicine (EuGMS) congress in September 2019, which showed a rapid deterioration of the mobility in the participants as measured by the 400-meter walk test (400MWT). The protocol amendment is subject to review and approval by the appropriate regulatory agencies (FDA and AFMPS).

Biophytis is using the same selection criteria for both the SARA-OBS study and the ongoing SARA-INT Phase 2b clinical trial evaluating the safety and efficacy of BIO101, for the treatment of patients with sarcopenia at risk of mobility disability. These criteria are more stringent than those utilized in previous sarcopenia studies.

The amendment also includes a plan for an unblinded interim analysis to reconfirm the deterioration of mobility over 6 months and to assess the likelihood of success of the SARA-INT study based on the revised patient population size.

In addition, the company provided the regulatory agencies with a routine update on Sarconeos (BIO101).

Sam Agus, Chief Medical Officer of Biophytis, said, "*Our analysis of the preliminary data from the SARA-OBS observational study has shown that we are recruiting the right patient population into the SARA-INT Phase 2b clinical trial, namely patients with severe sarcopenia that are at a high risk for mobility disability. We believe these patients have a significant unmet medical need as they are less likely to respond to exercise alone and are in need of a medication for the treatment of their disease. The results also show these patients experience a more rapid functional deterioration in mobility than originally expected, particularly in the 400-meter walk test, which is the primary endpoint in the SARA-INT clinical trial. Based on these findings we now expect the SARA-INT to show that BIO101 delivers a larger treatment effect versus placebo than we previously anticipated. Therefore, we have used these findings to file protocol amendments with the*

appropriate regulatory agencies, which, if approved, could allow us to make positive changes to the SARA-INT study design."

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.

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 six and 22 percent.

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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. A pediatric formulation of Sarconeos (BIO101) is being developed for the treatment of Duchenne muscular dystrophy (DMD), which Biophytis expects to be ready to enter the clinic for 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.

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