

## Biophytis Presents Preliminary Analysis of SARA-OBS study at the 12<sup>th</sup> Annual Congress of The Society on Sarcopenia, Cachexia and Wasting Disorders (SCWD) in Berlin, Germany

**Paris (France), Cambridge (Massachusetts, United States)**, December 9, 2019, 8:00 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 the presentation of the preliminary analysis of the SARA-OBS observational study, at the 12th international SCWD conference on cachexia, sarcopenia and muscle wasting which took place in Berlin, Germany, December 6-8<sup>th</sup>, 2019.

The presentation entitled, *SARA program: Preliminary Findings & Implications from SARA-OBS Study and Its Impact on SARA-INT study*, was given by Dr. Samuel Agus, Chief Medical Officer (CMO) of Biophytis, in the session L: *Late breaking clinical science and clinical trial update* on Saturday December 7, 2019.

The preliminary analysis of the SARA-OBS observational study population showed a rapid deterioration of the mobility in the participants as measured by the 400-meter walk test (400MWT), its primary endpoint. The results of the SARA-OBS trial confirmed that the more stringent inclusion criteria used in the SARA-OBS study and in the on-going Phase 2b SARA-INT trial lead to the selection of patients that are at a higher risk for mobility disability. This is in contrast to previous sarcopenia studies where a much broader population has been included.

These preliminary findings from the SARA-OBS study also mean that if Sarconeos (BIO101) is indeed beneficial for these patients, a larger difference will be seen between the treated participants and those who received placebo.

**Dr Samuel Agus, CMO of Biophytis**, said *"We are pleased to have the opportunity to present the SARA-OBS preliminary analysis at SCWD. The SARA-OBS study was designed to characterize a population of sarcopenic patients to be included in the SARA-INT Phase 2b study and the preliminary data shows that we are recruiting the right patient population, namely patients with severe sarcopenia that are at a high risk for mobility disability. Based on these preliminary findings we would expect the SARA-INT trial to show that Sarconeos (BIO101) delivers a larger treatment effect versus placebo than initially anticipated. These data provide us with greater confidence that the SARA-INT study will deliver a positive outcome and further emphasizes the potential of Sarconeos (BIO101) as a treatment for neuromuscular diseases."*

Biophytis filed a protocol amendment 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) to optimize the SARA-INT Phase 2b clinical trial for sarcopenia, based on the findings from the SARA-OBS study. The company is currently awaiting clearance of this amendment.

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### **About SARA-OBS**

The SARA-OBS clinical study evaluated the mobility, strength and physical activity of up to one hundred sarcopenic patients recruited from a dozen clinical centers in the U.S., Belgium, France and Italy over a 6-

month period. The study has been designed to characterize a population of sarcopenic patients to be included in the SARA-INT study Phase 2b. The recruitment was carried out following criteria defined by the Foundation for the National Institutes of Health: 6mn walk test, 400 meters gait speed test, electronically recorded patient-reported outcomes (ePROs): SF-36 QOL questionnaire, measures of muscle strength and muscle mass, plasmatic biomarkers.

### **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 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 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 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](http://www.biophytis.com).

### **Disclaimer**

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