

## Biophytis Opens 22<sup>nd</sup> Clinical Site in the SARA-INT Phase 2b Trial of Sarconeos (BIO101) for the Treatment of Sarcopenia

*Target number of clinical sites reached,  
including leading hospitals and geriatric centers in the US and Europe*

*Patient enrollment expected to complete in mid-2020*

Paris (France), Cambridge (Massachusetts, United States), October 4, 2019, 08:00 CEST - Biophytis SA (Euronext Growth Paris: ALBPS), a clinical-stage biotechnology company focused on the development of drug candidates for the treatment of age-related diseases, with a primary focus on neuromuscular diseases, announced today that the 22<sup>nd</sup> clinical site has been opened in the US for the SARA-INT clinical trial, a Phase 2b clinical trial evaluating the safety and efficacy of Biophytis' lead drug candidate, Sarconeos (BIO101), for the treatment of sarcopenia.

**Roger Fielding, PhD, Director of the Nutrition, Exercise Physiology & Sarcopenia Laboratory at Tufts University in Boston and Principal Investigator of SARA-INT trial** commented, *"The SARA-INT Phase 2 trial is investigating a new treatment for sarcopenia, a disease of aging which is characterized by loss of muscle mass and function. Following the supportive preliminary data, this trial will evaluate the efficacy of BIO101 on muscle function and mobility in older adults."*

The SARA-INT study is a multicenter double-blind, placebo-controlled, randomized interventional Phase 2b clinical trial evaluating Sarconeos (BIO101) in patients with sarcopenia at risk of mobility disability in the US and Europe. The primary objective of the Phase 2b trial is to evaluate 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. Sarcopenia is an age-related degeneration of skeletal muscle, which is characterized by a loss of muscle mass, strength and function in elderly people over the age of 65 leading to mobility disability and increased risk of adverse health events and hospitalization, and potential death.

The SARA-INT trial protocol, including the main study endpoints, was defined following a scientific opinion from the European Medicines Agency (EMA) and input from the Food & Drug Administration (FDA). The primary endpoint is the gait-speed over the 400-meter walk test (400MWT), which represents a measure of the participant's mobility function. Biophytis is still waiting for an authorization from the French drug agency, ANSM, to begin the study in France, which may lead to additional clinical sites being opened.

Biophytis' lead drug candidate, Sarconeos (BIO101), is an orally administered small molecule in development for the treatment of neuromuscular diseases. Preclinical data demonstrated that Sarconeos (BIO101) for the treatment of sarcopenia has beneficial effects on muscle function and increases muscle strength and mobility in animal models.

Sarconeos (BIO101) is thought to activate the MAS receptor in muscle cells, a key component of the renin-angiotensin system (RAS). The RAS is a fundamental endocrine system that is known to control fluid balance, blood pressure and cardio-vascular function. Importantly, the RAS is also involved in the regulation of smooth, cardiac and skeletal muscle metabolism and plays a key role in muscle function and mobility.

*“Reaching the targeted number of clinical centers in the SARA-INT trial is a significant milestone as we advance our lead drug candidate Sarconeos (BIO101),” said Stanislas Veillet, CEO of Biophytis. “We believe sarcopenia remains a unmet medical need due to the disability, cost and mortality it causes, and the fact that there are currently no approved medications to prevent or slowdown the disease. The SARA-INT trial is an important study as it is recruiting patients with severe sarcopenia who experience a clinically meaningful decrease in their mobility over a six-month period. We remain focused on activities to drive patient recruitment so that we can complete enrollment of the SARA-INT trial as expected in mid-2020.”*

Sarconeos (BIO101) is also being developed for the treatment of Duchene muscular dystrophy (DMD), a severe type of muscular dystrophy. Biophytis expects Sarconeos (BIO101) to be ready to enter the clinic for DMD in 2020, subject to regulatory approval.

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### **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 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 Sarconeos (BIO101) is being developed for the treatment of Duchenne muscular dystrophy (DMD). Biophytis expects Sarconeos (BIO101) to be ready to enter the clinic for DMD in 2020, subject to regulatory approval. 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).

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## Press Release

the two texts, the French language version shall prevail.

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Source: Biophytis