

Biophytis provides an update on SARA-INT, a Phase 2b clinical trial evaluating the efficacy of Sarconeos (BIO101) in the treatment of sarcopenia

Re opening of investigation sites in Belgium and in the US

Treatment period extended by 3 months based on a review of the DSMB and the favorable risk profile of Sarconeos (BIO101)

Paris (France), Cambridge (Massachusetts, United States), August 28, 2020, 6 p.m. CEST - Biophytis SA (Euronext Growth Paris: ALBPS), a clinical-stage biotechnology company specialized in the development of drug candidates for treatment of age-related diseases, including neuromuscular diseases, today provides an update on the SARA-INT clinical development program, a Phase 2b study evaluating the efficacy of Sarconeos (BIO101) in sarcopenia.

The last of the 231 patients to be included in the SARA-INT trial study was recruited in March 2020. Due to COVID-19, Biophytis had to adapt the SARA-INT protocol in order to ensure the continuity of the trial, in particular by:

- closing all on-site activities and
- organizing patient follow-up to take place at home.

These changes were based on recommendations from both the US Food and Drug Administration (FDA) guidance and the Data and Safety Monitoring Board (DSMB) designed to preserve patients' safety in ongoing clinical trials.

The Company announces today the re-opening of four of its sites in Belgium and the US. Other sites should re-open progressively depending on the local evolution of the pandemic. For sites that are not re-opening, treatment will be extended by 3 months based on a review of the DSMB and the favorable risk profile of Sarconeos (BIO101).

As a result of these protocol changes, and depending on the evolution of the pandemic, the last patient out from the SARA-INT study is now expected at the end of 2020.

The SARA-INT study elderly population is particularly vulnerable to the consequences of the COVID-19 pandemic. As a result, the final number of patients to be analyzed in the study will be reduced significantly. Despite this, the study is expected to provide sufficient data to give a clear view of the potential benefits of Sarconeos (BIO101). To date, 64 patients are already qualified as "completers" and accounted for in the final analysis.

As a result of the delays incurred due to the COVID-19 pandemic, and provided top line results to come, no interim analysis will be undertaken by the DSMB.

Stanislas Veillet, Chief Executive Officer, says: *“We are very pleased that some sites have now re-opened and that the FDA and AFMPS in Belgium, and the DSMB approved the extension of the treatment period in the SARA-INT Phase 2 study by three months based on Sarconeos (BIO101) favorable risk profile. The team at Biophytis continues to be very active in ensuring the best follow-up of patients enrolled into the study despite the COVID-19 crisis. Following recent measures to ease the confinement rules in the US and in Belgium Biophytis has updated its guidance for conducting follow-up visits and this has been reflected in the study’s protocol. We are confident to have our last patient out by the end of this year in order to announce top line results by H1 2021.”*

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 6 and 22 percent.

About BIOPHYTIS

Biophytis SA is a clinical-stage biotechnology company specialized in the development of drug candidates to slow down degenerative processes and improve functional abilities in patients with age-related diseases, including neuromuscular diseases.

Sarconeos (BIO101), our leading drug candidate, is a small molecule, administered orally, currently in clinical Phase 2b in sarcopenia (SARA-INT) in the United States and Europe. A pediatric formulation of Sarconeos (BIO101) is being developed for the treatment of Duchenne Muscular Dystrophy (DMD). The company plans to start the clinical development (MYODA) in H2 2020.

Sarconeos (BIO101) is also being developed as a treatment for COVID-19. The Company has received approval from ANSM (France), FAMHP (Belgium), ANVISA (Brazil), the MHRA (UK) and the FDA in the US to begin the Phase 2/3 clinical trial (COVA) to evaluate Sarconeos (BIO101) as a potential treatment for respiratory failure associated with COVID-19.

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

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