Press release

Biophytis receives a positive opinion for its SARA-31 phase 3 study in sarcopenia in Europe

Paris (France) and Cambridge (Massachusetts, USA), August 8, 2023 – 07:00 am CET – Biophytis SA (Nasdaq CM : BPTS, Euronext Growth Paris : ALBPS), («Biophytis»), a clinical-stage biotechnology company specialized in the development of therapeutics that are aimed at slowing the degenerative processes associated with aging and improving functional outcomes for patients suffering from age-related diseases, including severe respiratory failure in patients suffering from COVID-19, today announced that it has received a positive opinion from Belgian authorities to conduct its SARA-31 program, which will be the first phase 3 study ever launched in sarcopenia.

The launch of the Phase 3 program follows the promising results obtained in the SARA-INT Phase 2b study, and the scientific advice given in 2022 by the EMA (European Medicine Agency), which helped define the conditions for starting such a study in Europe, specifying the Phase 3 protocol. Final authorization depends on a positive opinion from the Ethics Committee in Belgium. A similar application has been filed with the FDA (Food and Drug Administration) to start this study in the United States, with a response expected in the coming weeks. Further authorizations may be requested in other countries, depending on the needs of the study.

Stanislas Veillet, Chief Executive Officer of Biophytis, commented: *"This opinion is a major step forward in our efforts to treat sarcopenia, an age-related neuromuscular disease characterized by the progressive loss of muscle strength and walking in the elderly, leading to loss of autonomy and reduced life expectancy. Despite the enormous medical need posed by this disease, no drug is currently approved anywhere in the world. Today, we are putting our pioneering position in this field into practice by obtaining, for the first time, a positive opinion from a regulatory agency to conduct a phase 3 clinical trial in this debilitating geriatric disease, which affects more than 30 million patients worldwide".*

About SARA-31

The aim of phase 3 is to evaluate the efficiency and safety of Sarconeos (BIO101) in the treatment of sarcopenic patients at risk of motor disability. Around 900 patients aged over 65 with severe sarcopenia (3 ≤ SPPB ≤ 7) with low walking speed (4-meter walking speed ≤ 0.8 m/s) and low grip strength (HGS < 20kg for women and < 35.5 kg for men) will be included. They will be treated for a minimum of 12 months and a maximum of 36 months, receiving either placebo or 350mg of Sarconeos (BIO101) twice daily. The main criterion will be an assessment of the risk of Major Mobility Disability (MMD), measured by the ability to walk 400m in less than 15 minutes. This main criterion will be supplemented by the following secondary criteria: walking speed (4-m walking speed from the SPPB - Short Physical Performance Battery - test), grip strength (HGS) and patient-reported quality of life (Patient Reported Outcome SarQol, a questionnaire specifically developed for sarcopenia).

Roger A. Fielding, PhD, sarcopenia expert and laboratory director at Tufts University, Boston, will be the principal investigator of the SARA-31 study. He is continuing his contribution to the Sarconeos (BIO101) clinical development program in this indication.

About BIOPHYTIS

Biophytis SA is a clinical-stage biotechnology company specializing in the development of drug candidates for age-related diseases. Sarconeos (BIO101), our lead drug candidate, is a small molecule in development for age-related neuromuscular (sarcopenia and Duchenne muscular dystrophy) and cardiorespiratory (Covid-19) diseases. Promising clinical results were obtained in the treatment of sarcopenia in an international phase 2 study, enabling the launch of a phase 3 study in this indication (SARA project). The safety and efficacy of Sarconeos (BIO101) in the treatment of severe COVID-19 were studied in a positive international phase 2-3 clinical trial (COVA project), enabling the preparation of conditional marketing authorization (CMA) applications in Europe and Emergency Use Authorization (EUA) applications in the United States. A pediatric formulation of Sarconeos (BIO101) is currently being developed for the treatment of Duchenne Muscular Dystrophy (DMD, MYODA project). The company is based in Paris, France, and Cambridge, Massachusetts. The Company's ordinary shares are listed on Euronext Growth (Ticker: ALBPS -ISIN: FR0012816825) and the ADSs (American Depositary Shares) are listed on Nasdaq Capital Market (Ticker BPTS - ISIN: US09076G1040).
For more information, visit www.biophytis.com

Disclaimer

This press release contains forward-looking statements. Forward-looking statements include all statements that are not historical facts. In some cases, you can identify these forward-looking statements by the use of words such as "outlook," "believes," "expects," "potential," "continues," "may," "will," "should," "could," "seeks," "predicts," "intends," "trends," "plans," "estimates," "anticipates" or the negative version of these words or other comparable words. Such forward- looking statements are based on assumptions that Biophytis considers to be reasonable. However, there can be no assurance that the statements contained in such forward-looking statements will be verified, which are subject to various risks and uncertainties. The forward-looking statements contained in this press release are also subject to risks not yet known to Biophytis or not currently considered material by Biophytis. Accordingly, there are or will be important factors that could cause actual outcomes or results to differ materially from those indicated in these statements. Please also refer to the "Risk and uncertainties the Company is to face» section from the Company's 2022 Financial Report available on BIOPHYTIS website (www.biophytis.com) and as exposed in the "Risk Factors" section of form 20-F as well as other forms filed with the SEC (Securities and Exchange Commission, USA). We undertake no obligation to publicly update or review any forward-looking statement, whether as a result of new information, future developments or otherwise, except as required by law.

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