

## **Biophytis announces next regulatory steps in Europe and the United States for its COVA project**

**Paris (France) and Cambridge (Massachusetts, USA), August 16, 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, announced today that it has received feedback from the European Medicines Agency (EMA) and the Food and Drug Administration (FDA) enabling it to plan the next regulatory steps for its COVA project dedicated to the development of Sarconeos (BIO101) for severe forms of Covid-19.

After filing requests for pre-submission meetings with both agencies in recent weeks, the company will now request a scientific advice meeting in Europe and a Type B meeting in the United States. The purpose of these meetings will be to gather recommendations from the EMA and the FDA to fine-tune COVA's development plan prior to marketing approval.

These discussions will enable Biophytis to present the available data (preclinical, clinical, product and industrialization) and specify the additional information to be provided in the context of marketing authorization applications, in particularly the design of a confirmatory phase 3 clinical study.

Biophytis will also present the agencies with the possibility of extending the scope of its indication to viral respiratory pathologies other than Covid-19, notably influenza, based on its non-specific mechanism of action. This extension would significantly increase the number of patients eligible for treatment and optimize the commercial potential of Sarconeos (BIO101).

### **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](http://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](http://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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