

## Biophytis has requested a pre-submission meeting with the FDA for an Emergency Use Authorization of Sarconeos (BIO101) for the treatment of COVID-19

Paris (France) and Cambridge (Massachusetts, USA), July 20, 2023 – 07:00am 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 filed for a pre-submission meeting request with the *Food and Drug Administration* (FDA) to discuss filing for Emergency Use Authorization (EUA) in the United States for Sarconeos (BIO101) in the treatment of severe forms of COVID-19.

This is a further key step in defining the conditions for rapid market access in the United States for Sarconeos (BIO101) in the treatment of severe forms of COVID-19, following the similar process initiated with the *European Medicine Agency* (EMA) in May, in a context where COVID-19 is still associated with a public health problem in the United States and in Europe.

**Stanislas Veillet, Chief Executive Officer of Biophytis, commented:** *“We are actively pursuing our roadmap by initiating discussions with the FDA to bring our drug candidate to patients suffering from severe forms of COVID-19 in the United States. Like influenza, this pathology has become an endemic respiratory infectious disease that can lead to Acute Respiratory Distress Syndrome (ARDS) in elderly, immunocompromised or co-morbid patients. According to the WHO, the medical need remains high, with several thousand deaths per week in the United States and Europe. In this context, the positive clinical results of the phase 2-3 COVA study, with a 44% reduction in the risk of respiratory failure or early death, suggests that Sarconeos (BIO101) could become an important new therapeutic option alongside antiviral or anti-inflammatory treatments. We look forward to starting discussions with the FDA, and depending on feedback from this agency, we could consider filing an Emergency Use Application by the end of 2023 or in the first half of 2024.”*

### 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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