

## **Biophytis received approval from ANVISA (Brazil) to give access to Sarconeos (BIO101) to hospitalized COVID-19 patients through an Expanded Access Program**

- ANVISA (Brazilian Health Authority) approved Biophytis' Expanded Access Program (EAP) for hospitalized patients with severe COVID-19 and mechanically ventilated in Intensive Care Unit
- Sarconeos (BIO101) treatment will be given to a maximum of 80 patients mechanically ventilated in Intensive Care Units (ICUs) of Brazilian hospitals
- In parallel, Sarconeos (BIO101) is being evaluated in a Phase 2-3 study (COVA), in Europe, Latin America, and the US, for the treatment of non-intubated hospitalized patients with severe respiratory manifestations of COVID-19

Paris, France, and Cambridge, Massachusetts, USA – February 03, 2022, 08:00 a.m. CET – Biophytis SA (NasdaqCM: BPTS, Euronext Growth Paris: ALBPS), (“Biophytis” or the “company”) a clinical-stage biotechnology company, based on Sorbonne University campus and focused on the development of therapeutics that slow the degenerative processes associated with aging, including severe respiratory failure in patients suffering from COVID-19, today announces that it has received approval from the ANVISA (Brazilian health authority) for its Expanded Access Program (EAP) to treat hospitalized patients with severe COVID-19 with Sarconeos (BIO101). A maximum of 80 patients who are mechanically ventilated in Intensive Care Unit of Brazilian hospitals will be treated with Sarconeos (BIO101) for up to 28 days to prevent further deterioration and mortality.

Stanislas Veillet, CEO of Biophytis said: *“Making Sarconeos (BIO101) available to critically ill patients in the ICU with severe Covid-19 is planned to be the next step towards bringing our product to the market as quickly as possible. This program will generate important new information about the safety of Sarconeos (BIO101) as well as explore the potential effectiveness in mechanically ventilated patients, a novel potential indication”.*

Whilst the numbers of hospitalized patients with severe COVID-19 is again steeply increasing, there are still very few options available for the treatment of severe Covid-19 disease, including when respiratory insufficiency is necessitating mechanical ventilation in the ICU. This EAP, giving access to Sarconeos (BIO101) to most severe cases of COVID-19 patients is complementing Biophytis effort to participate to the therapeutic armamentarium against COVID-19 along with the ongoing COVA Phase 2-3 study. The COVA study (the Principal Investigator in Brazil is Dr Ludhmila Hajjar, USP, InCor, Sao Paulo, Brazil), is evaluating Sarconeos (BIO101) for the treatment of severe respiratory manifestations of COVID-19 in non-intubated hospitalized patients.

Dr Suzana Lobo, head of the Intensive Care Division - Hospital de Base and FAMERP Medical School in S j Rio Preto- SP- Brazil, and EAP coordinating physician, said: *“Brazil is now the third in the ranking of Covid-19 cases in the world and second in number of deaths. Following the omicron surge we are now facing again a steep increase in the number of cases which has led again to an*



*increasing number of ICU admissions despite our advances in vaccination. Besides corticosteroids and the best standard of care, up to now we have no options for patients on mechanical ventilation in which mortality rates remain at unacceptable levels. I am happy to collaborate in this new phase of application of this medicine that explores very innovative pathways in the treatment of severe cases and brings hope for better outcomes”.*

ANVISA’s approval of an EAP is mainly based on the following criteria:

- The product is aimed at patients with serious debilitating and/or life-threatening disease.
- There is no satisfactory therapeutic alternative with products registered in Brazil.
- The authorization to use the product is delivered based on the request, and only under the responsibility of the prescribing practitioner, as it is expected to deliver a significant benefit to the patient.

Brazil is the first country to approve the EAP to give access to Sarconeos (BIO101) to hospitalized COVID-19 patients. Based on this first approval and upcoming completion of the COVA study during H1 2022, Biophytis is willing to extend the EAP submission to other territories in the world.

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### **About BIOPHYTIS**

Biophytis SA is a clinical-stage biotechnology company specialized in the development of therapeutics that are aimed at slowing the degenerative processes associated with aging, including severe respiratory failure in patients suffering from COVID-19.

Sarconeos (BIO101), our leading drug candidate, is a small molecule, administered orally, being developed as a treatment for sarcopenia with a positive Phase 2 clinical trial performed in the United States and Europe (SARA-INT). It is also being studied in a clinical two-part Phase 2-3 study (COVA) for the treatment of severe respiratory manifestations of COVID-19 in Europe, Latin America, and the US. A pediatric formulation of Sarconeos (BIO101) is being developed for the treatment of Duchenne Muscular Dystrophy (DMD).

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 ADS (American Depositary Shares) are listed on Nasdaq (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 "Risks and uncertainties the Company is to face" section from the Company's 2021 Half Year Report available on BIOPHYTIS website ([www.biophytis.com](http://www.biophytis.com)) and as exposed in the "Risks 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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