

## Biophytis Completed Recruitment of 155 Participants to the COVA Phase 2-3 Study with Sarconeos (BIO101) in COVID-19 allowing the 2<sup>nd</sup> Interim Analysis

- This 2<sup>nd</sup> interim analysis is to be performed by the independent DMC (Data Monitoring Committee) based on safety and efficacy data
- The Company is to report the recommendation from the DMC based on its review of second interim analysis by end of Q2 2021, subject to any COVID-19-related delays

Paris, France, Cambridge (Massachusetts, United States), May 12, 2021 - 8AM CET -- Biophytis SA (Nasdaq CM: BPTS, Euronext Growth Paris: ALBPS), (“Biophytis” or the “Company”), - Biophytis SA (NasdaqCM: BPTS, Euronext Growth Paris: ALBPS), a clinical-stage biotechnology company focused on 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 announces it has recruited the 155th participant for Part 2 of its COVA Phase 2-3 study of Sarconeos (BIO101) in patients infected with COVID-19.

Recruitment of the 155<sup>th</sup> participant allows for the independent Data Monitoring Committee (DMC) to conduct its second interim analysis, based on safety and efficacy data, for the continuation of the trial in case of favorable results. The Company is to report the recommendations of the DMC based on its review of the second interim analysis results by the end of Q2 2021.

The DMC previously delivered a favorable opinion in March on the safety of Sarconeos (BIO101) in COVID-19 and recommended the continuation of the study into Part 2, following the scheduled interim analysis of the 50 participants in Part 1 of the COVA study.

Recruitment into Part 2 of the study continues to proceed in France and Brazil to complete enrollment of 310 participants, with the aim of filing for Emergency Use Authorization with the US Food and Drug Administration (FDA) and Conditional Approval with the European Medicines Agency (EMA) in Q3 2021. The final study results are expected in Q3 2021, subject to any COVID-19-related delays and the impact of the pandemic.

**Stanislas Veillet, President and CEO of Biophytis**, said: *“Completion of recruitment of the 155<sup>th</sup> patient is an important milestone for Biophytis as we will be able to measure the therapeutic potential of Sarconeos (BIO101) in COVID-19. We are now looking forward to the second interim analysis, and hope the DMC will recommend the continuation of our Phase 2-3 COVA trial upon favorable review of the safety and efficacy data.”*

The COVA clinical program (clinicaltrials.gov identifier NCT04472728) is a global, multicenter, double-blind, placebo-controlled, group-sequential and adaptive design two-part study. This



## Press release

Phase 2-3 study assesses Sarconeos (BIO101) in patients aged 45 and older, hospitalized with severe respiratory manifestations of COVID-19. The 155 participants were recruited in 34 centers in 4 countries: the US, Brazil, France and Belgium.

Part 1 of the COVA Study is a Phase 2 exploratory proof of concept study providing preliminary data on the safety, tolerability, and activity of Sarconeos (BIO101) in 50 patients with severe respiratory manifestations related to COVID-19.

Part 2 of the COVA Study is a Phase 3 randomized study investigating the safety and efficacy of Sarconeos (BIO101) on the respiratory function of 310 COVID-19 participants, or up to 465 participants, including the 50 participants from Part 1 of the study.

The final sample size will depend upon DMC recommendations from the second interim analysis.

### 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 and improving functional outcomes for patients suffering from age-related diseases, 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 in a Phase 2 clinical trial 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 common shares are listed on Euronext Growth (Ticker: ALBPS -ISIN: FR0012816825) and ADSs 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. These forward-looking statements include statements regarding Biophytis' anticipated timing for its Interim Analysis of Part 1 and release of full study results. 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 including, without limitation, delays in participant recruitment or retention, interruptions in sourcing or supply chain, its ability to obtain the necessary regulatory authorizations, COVID-19-related delays, and the impact of the current pandemic on the Company's clinical trials. The forward-looking statements contained in this press release are also subject to risks not yet known to Biophytis



## Press release

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. In France, please also refer to the "Risk Factors" section of the Company's Annual 2020 Report available on BIOPHYTIS website ([www.biophytis.com](http://www.biophytis.com)). 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.

### **Biophytis Contact for Investor Relations**

Evelyne Nguyen, CFO

[evelyne.nguyen@biophytis.com](mailto:evelyne.nguyen@biophytis.com)

### **Media contact**

*LifeSci Advisors*

Sophie Baumont/Chris Maggos

E: [sophie@lifesciadvisors.com](mailto:sophie@lifesciadvisors.com)

T: +33 6 27 74 74 49

### **Investor Relations**

*LifeSci Advisors, LLC*

Ligia Vela-Reid

E: [lvela-reid@lifesciadvisors.com](mailto:lvela-reid@lifesciadvisors.com)