Press Release

Biophytis Receives Favorable Recommendation From Data Monitoring Committee (DMC) Based on Safety Analysis of Sarconeos (BIO101) to Continue Patient Recruitment in the COVA Study in COVID-19

- The independent DMC (Data Monitoring Committee) of the COVA study recommends to continue patients recruitment into Part 2 of the phase 2-3 study following randomization of the first 155 patients
- Efficacy data from the second Interim Analysis is expected to be reviewed by DMC in Q3 2021
- Top line results of the full study on 310 patients are expected in Q4 2021, depending on COVID-19 pandemic

Paris (France), Cambridge (Massachusetts, U.S.), Agust 16, 2021 - 8:00 a.m. CET - Biophytis SA (NasdaqCM: BPTS, Euronext Growth Paris: ALBPS), a clinical-stage biotechnology company focused on the development of therapeutics that slow the degenerative processes associated with aging and improve functional outcomes for patients suffering from age-related diseases, including severe respiratory failure in patients suffering from COVID-19, today announces the recommendation by the Data Monitoring Committee (DMC) to continue patient recruitment into part 2 of the COVA study with the protocol unmodified after review of safety data.

The independent DMC meeting was dedicated to the analysis of safety data from the first 155 patients randomized in the Phase 2-3 COVA Study in COVID-19. The efficacy data of those 155 patients will be reviewed by the DMC in Q3 2021 as part of the second Interim analysis to make recommendation regarding futility and final sample size.
As of today 191 patients have been randomized in 36 clinical centers opened in the USA, Brasil, France and Belgium.

Stanislas Veillet, CEO of Biophytis declared: "The DMC recommendation to continue the COVA study with an unchanged protocole based on the safety analysis of the first 155 patients is a very positive news. It's confirming the good safety profile of Sarconeos (BIO101) in hospitalized COVID-19 patients. We are now waiting for DMC recommendation based on efficacy analysis in Q3 2021. The COVA team is working hard to complete recruitment of the 310 patients and report top line results in Q4 of 2021."

The COVA clinical program (clinicaltrials.gov identifier: NCT04472728) is a global, multicentric, double-blind, placebo-controlled, group-sequential, and adaptive design two-part Phase 2-3 study assessing Sarconeos (BIO101) in patients aged 45 and older, hospitalized with severe respiratory manifestations of COVID-19.

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

Part 2 of the COVA Study will be a Phase 3 pivotal randomized study investigating the safety and efficacy of Sarconeos (BIO101) on the respiratory function of 310 or up to 465 COVID-19 patients (including the 50 patients from Part 1 of the study).
The final sample size will depend upon DMC recommendations from the second interim analysis.

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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 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 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

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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 2020 Annual Report available on BIOPHYTIS website (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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