

Biophytis Announces the Start of Patient Recruitment in Brazil and the USA for Part 2 of the Phase 2-3 COVA Trial (“COVA Study”)

- *Patient recruitment in Part 2 of the COVA Study will begin in most clinical centers in Brazil and the United States*
- *Interim Analysis of Part 1 is expected in Q1 2021*
- *Results from the full study (Part 1 and Part 2) are expected in Q2 2021*

Paris (France), Cambridge (Massachusetts, U.S.), February 3, 2021, 8:00 a.m. CET - Biophytis SA (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 that patient recruitment at most clinical centers in Brazil and the United States will begin for Part 2 of its COVA Study assessing Sarconeos (BIO101) as a potential treatment for acute respiratory failure associated with COVID-19.

Enrollment for Part 1 of the COVA Study has been completed with 50 patients recruited in 4 countries: Brazil, the USA, Belgium, and France. Following the Data Monitoring Committee (“DMC”) recommendation to begin the recruitment for Part 2, authorization is being obtained from regulatory authorities (national regulatory agencies and/or central IRB and/or local Ethics Committees) in Brazil and the USA for the start of Part 2. Similar authorizations are being pursued in France, Belgium and the UK.

Stanislas Veillet, Chief Executive Officer of Biophytis, said: *“We are extremely pleased to start recruiting patients for Part 2 at most clinical centers in Brazil and the USA.”* He added: *“There continues to be an unmet need for new COVID-19 treatment options for elderly patients, or patients with co-morbidities, who will continue to be at high risk of developing severe respiratory manifestations requiring hospitalization.”*

The COVA Study (clinicaltrials.gov identifier: NCT04472728, and EudraCT identifier: 2020-001498-63) is a global, multicenter, 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, tolerability and activity of Sarconeos (BIO101) in 50 hospitalized patients with severe respiratory manifestations related to COVID-19. The Interim Analysis of Part 1 is expected in Q1 2021, subject to any COVID-19 related delays and the impact of the current pandemic on our operational capabilities.



Part 2 of the COVA Study is a Phase 3 pivotal randomized study investigating the safety and efficacy of Sarconeos (BIO101) on the respiratory function from 310 COVID-19 patients (including the 50 patients from Part 1 of the study). The full study results (Part 1 and Part 2) are expected in Q2 2021, subject to any delays in patient recruitment or retention, interruptions in sourcing or supply chain, regulatory authorizations, COVID-19-related delays, and the impact of the current pandemic.

About BIOPHYTIS

Biophytis SA is a clinical-stage biotechnology company specialized in 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. 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 the Euronext Growth Paris market (Ticker: ALBPS -ISIN: FR0012816825). For more information visit 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 patient 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 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 2019 Report and the Company's Half Year 2020 Report available on BIOPHYTIS website (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.



This press release was written in French and English; If there is a difference between the texts, the French version will prevail.

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