

Biophytis receives DMC recommendation for starting recruitment for Part 2 of its Phase 2-3 COVA study in COVID-19

- *The independent Data Monitoring Committee (DMC) of the COVA study recommends start of recruitment of Part 2 of the two-part Phase 2-3 Study (“the COVA Study”)*
- *Patient recruitment for Part 2 of the COVA Study will start as soon as regulatory/ethics approvals or permissions are obtained in the relevant jurisdictions*
- *Interim Analysis on Part 1 is expected in Q1 2021.*

Paris (France), Cambridge (Massachusetts, U.S.), January 19 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 the recommendation by the DMC to start recruitment for Part 2 of Phase 2-3 of the COVA Study. The COVA Study assesses Sarconeos (BIO101) as a potential treatment for acute respiratory failure associated with COVID-19.

The DMC’s recommendation is based on its review of the safety data analysis from the first 20 patients enrolled in the study. Based on the DMC’s recommendation, Biophytis intends to start patient recruitment for Part 2 of the COVA Study in countries where applicable regulatory approvals or permissions, including Institutional Review Board/Ethics Committee approvals, are obtained.

Stanislas Veillet, Chief Executive Officer of Biophytis, said: *“We are extremely pleased to receive the DMC’s recommendation to commence recruitment for Part 2 of the COVA Study. With the deteriorating COVID-19 situation around the world, there is a clear need for new treatment options for elderly patients, or patients with co-morbidities, who are expected to continue to be at high risk of developing severe respiratory manifestations requiring hospitalization, even while vaccines are being rolled-out.”*

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 COVID-19 patients (including the 50 patients from Part 1 of the study).

Results from the full study (Part 1 and Part 2) are expected in Q2 2021, subject to any 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

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This press release contains forward-looking statements. While the Company considers its projections to be based on reasonable assumptions, these forward-looking statements may be called into question by a number of hazards and uncertainties, so that actual results may differ materially from those anticipated in such forward-looking statements. For a description of the risks and uncertainties likely to affect the results, BIOPHYTIS' financial position, performance or achievements and thus cause a change from the forward-looking statements, please 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).

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