Press release

Biophytis Secures the Manufacturing of Sarconeos (BIO101) for COVID-19 with a Global CDMO & Announces the Next Milestones for the COVA Phase 2-3 Study

- The Company signed contracts for the manufacturing of registration batches in view of the potential application for Emergency Use Authorization to FDA and/or Conditional Marketing Authorization to EMA
- The 155th patient has completed treatment in Part 2 of the COVA Phase 2-3 study and results of second interim analysis are expected in Q3 2021
- The full results of the study and the filing for market authorization are now scheduled for Q4 2021.

Paris, France, Cambridge (Massachusetts, United States), June 30th 2021, 11 pm CET – Biophytis SA (Nasdaq CM: BPTS, Euronext Growth Paris: ALBPS), ("Biophytis" or the "company"), 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 secured contracts with a major global Custom Development and Manufacturing Organization (CDMO) for the manufacturing of registration batches of Sarconeos (BIO101). These contracts were signed in preparation of the potential filing of the product in COVID-19 for Emergency Use Authorization with FDA, or Conditional Marketing Authorization with EMA. The Company also announces the following next milestones:

- With the 155th patient for Part 2 of the COVA Phase 2-3 study with Sarconeos (BIO101) in patients infected with COVID-19 having completed the treatment on May 24 2021, data management and bio statistic activities are ongoing before submitting the results to the DMC (Data Monitoring Committee). Results of this second interim analysis (IA2) as regards to safety and efficacy are now expected in Q3 2021. The DMC previously delivered a favorable opinion in March 2021 on the safety of Sarconeos (BIO101) in COVID-19, following the first interim analysis of the 50 participants in Part 1 of the COVA study.

- Beyond the second interim analysis based on 155 patients, the Company is pursuing the recruitment of patients in the context of pandemic slow-down and progress of vaccination campaign in Europe and the USA. 176 patients have been recruited in total over the 310 required for the release of the full results. Top line results for the full study are now expected in Q4 2021, in view of a potential filing for Emergency Use Authorization and Conditional market Approval applications respectively with FDA and EMA by year end. Commercialization should then start beginning of 2022.

Press release

Stanislas Veillet, Chief Executive Officer of Biophytis, said: *"We are very pleased to have secured with a world-renowned manufacturer a new contractual framework in order to get us prepared for the next steps of Sarconeos (BIO101). Our goal is to rapidly scale up our supply capacity, should we receive approval for Sarconeos (BIO101) in COVID-19. We also progressed in the clinics with our last patient counting for the second interim analysis (IA2) having terminated his treatment. We are now very concentrated in getting the results for this IA2 by Q3 2021. Assuming positive data from the COVA trial, filing for Emergency Use Authorization with the FDA, and Conditional Marketing Authorization with EMA is now planned by the end of the year and if granted, commercialization could possibly start by the beginning of 2022. The new timelines do not change our commitments towards bringing a new treatment to hospitalized patients with COVID-19 and have no impact on Biophytis' overall strategy. We do believe despite vaccination campaigns, the medical need will persist. Therefore we are still actively engaged in the fight against this pandemic."*

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 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

Press release

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 various Sarconeos (BIO101) clinical trials and expectations regarding commercialization. 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. Please refer to the "Risk Factors" section of the Company's Annual 2020 Report available on BIOPHYTIS website (www.biophytis.com) and to the risks discussed in the Company's registration statement on Form F-1 and other reports filed with the Securities and Exchange Commission (the "SEC"). 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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