Biophytis

Press Release

Biophytis –Upcoming Potential Value Generating Milestones

- *COVA – Patient recruitment ramping up for this two-part Phase 2/3 study assessing Sarconeos (BIO101) for the treatment of severe respiratory manifestation of COVID-19*

  - ✓ *Completion of trial enrollment (Part 1) anticipated by end of December 2020*
  - ✓ *Interim Analysis and completion of trial enrollment (Part 2) expected in Q1 2021*
  - ✓ *Topline results of the full study expected in Q2 2021*
  - ✓ *Positive COVA results should allow filing for Emergency Use Authorizations (EUA) with the FDA in the US & conditional marketing authorization with the European Medicines Agency (EMA) in Europe for Sarconeos (BIO101)*

- *SARA-INT - Phase 2 study for the treatment of sarcopenia on track. Last-patient last visit planned end of December 2020. Topline trial results expected in H1 2021*

- *MYODA – Start of Phase 1 study for the treatment of Duchenne Muscular Dystrophy (DMD) expected in H1 2021, depending on the COVID-19 pandemic evolution*

Paris (France), Cambridge (Massachusetts, U.S.), December 3, 2020, 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 provides an update on its clinical developments and an outlook for the coming year.

Stanislas Veillet, **Chief Executive Officer,** stated: "*Older patients or patients with co-morbidities are expected to continue to be at high risk of developing severe respiratory manifestations requiring hospitalization, particularly in light of the recent acceleration of coronavirus cases in both Europe and the Americas. We now expect to complete enrollment of Part 1 of the COVA trial in the coming weeks and Part 2 in Q1 2021. Topline results of the full study are projected for Q2 2021.*

If the COVA trial is successful, we expect to submit Sarconeos (BIO101) for Emergency Use Authorization (EUA) with the US FDA and conditional marketing authorization with the European Medicines Agency (EMA).

We are on track with our SARA-INT trial and expect that our last patient will exit the study in the coming weeks. This would allow us to report the first results from the Phase 2 trial in H1 2021 and start planning for a potential Phase 3 trial."

Clinical development update:

COVA- Phase 2/3 COVA study for acute respiratory failure associated with COVID-19

The COVA clinical program (clinicaltrials.gov identifier *NCT04472728*) is a global, multicentric, double-blind, placebo-controlled, group-sequential and adaptive two-part Phase 2-3 study assessing Sarconeos (BIO101) in patients aged 45 and older, infected with SARS-CoV-2.

This pivotal multinational clinical trial is being conducted in two parts, the first of which will assess the treatment safety and provide an indication of activity of Sarconeos (BIO101) in 50 hospitalized patients. The study is designed to evaluate the efficacy and the safety of Sarconeos (BIO101) as a treatment to prevent further deterioration of patients with COVID-19-related respiratory failure, which could otherwise require admission to the intensive care units and ventilation.

The first part of the study is a Phase 2 exploratory proof of concept study to provide preliminary data on the activity, safety and tolerability of Sarconeos (BIO101) in 50 hospitalized patients with severe respiratory manifestations related to COVID-19. Patient recruitment is accelerating in 15 sites in Belgium, France, Brazil and the US. Our objective is to activate around 30 sites in the study before the end of the year. Biophytis expects enrolment of Part 1 of the study to be completed in the coming weeks.

The second part of the study will investigate 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).

Topline results from the full study (Part 1 and Part 2) are expected in Q2 2021.

Following positive data and the analysis and recommendation of an independent Data Monitoring Committee (DMC) Biophytis expects to submit Sarconeos (BIO101) for Emergency Use Authorization (EUA) with the US Food and Drug Administration (FDA) and for conditional marketing authorization with the European Medicines Agency (EMA) in Q2 2021.

SARA clinical program in sarcopenia

The lockdowns in Belgium and several American states (California and New York in particular) as a result of the COVID-19 pandemic have had a significant impact on the SARA-INT study.

Biophytis has had to adapt the SARA-INT protocol in order to ensure the continuity of the trial, while preserving the health of patients and adapting to the restrictions on movement imposed by governments and health authorities.

This has been achieved by:

- closing all on-site activities
- organizing patient follow-ups to take place at home.
- expanding the treatment from 6 to 9 months for some patients

Most sites have been reopened and the majority of the patients have completed the study. The last patient out from the SARA-INT study is now expected in the coming weeks. The topline results are expected in H1 2021.

MYODA clinical program in Duchenne muscular dystrophy (DMD)

The MYODA clinical program is a global, double-blind, placebo-controlled, group-sequential, Phase 1-3 clinical study, to evaluate the safety and efficacy of a pediatric formulation of Sarconeos (BIO101) in non-ambulatory patients with DMD and signs of respiratory deterioration.

Biophytis had received an IND "may proceed" letter from the US FDA and approval from the Belgian regulatory agency, Federal Agency for Medicines and Health Products (FAMHP), to start the clinical study of its product Sarconeos (BIO101) in non-ambulatory patients with DMD. FAMHP also cleared a protocol adjustment that changed respiratory function to the primary endpoint.

Biophytis amended the protocol to address the FDA's comments that were included in the IND "may proceed" letter regarding the study population and the primary endpoint. The Company will submit the revised protocol to the FDA for review.

However, due to the continued pandemic and the acceleration of COVID-19 cases in Belgium and the US, Biophytis has decided to delay the MYODA trial, which we hope to start in H1 2021 (pending the COVID-19 pandemic evolution and its effects on operational capabilities).

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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. 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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