Press release

Biophytis provides an update on its early access programs for Sarconeos (BIO101) in the treatment of severe forms of COVID-19

Paris (France) and Cambridge (Massachusetts, USA), September 19, 2023 – 07:00 am CET – Biophytis SA (Nasdaq CM : BPTS, Euronext Growth Paris : ALBPS), («Biophytis»), 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, today announced that it has received a response from the French National Authority for Health (HAS) to its request for Early Access Authorization in France for patients suffering from severe forms of COVID-19 and provides an update on its strategy in other countries.

After examining the Early Access Authorization request file submitted at the end of May 2023, HAS considered that the Company had not provided sufficient data allowing it to evaluate precisely the benefit vs. risk ratio and to authorize the treatment of patients with severe forms of COVID-19, despite the statistically significant results of the phase 2-3 COVA study. The Company must therefore complete the file by providing in particular certain results of pharmaceutical studies, in progress with its industrial partner Sequens, as well as certain additional data and scientific arguments relating to its phase 2-3 COVA study. On the basis of these various elements, it is planned to resubmit the application to the HAS in the first quarter of 2024, with pharmaceutical partner Intsel Chimos, depending on the progress made in the development plan.

At the same time, Biophytis is taking steps in Brazil to confirm the early access authorization obtained in early 2022 that was interrupted pending publication of the full results of the COVA study. This new authorization is expected by the end of the year.

Finally, the Company is exploring the possibilities of launching early access programs in other key countries in Europe, in order to best respond to the medical need in a pathology that has become endemic.

About BIOPHYTIS

Biophytis SA is a clinical-stage biotechnology company specializing in the development of drug candidates for age-related diseases. Sarconeos (BIO101), our lead drug candidate, is a small molecule in development for age-related neuromuscular (sarcopenia and Duchenne muscular dystrophy) and cardiorespiratory (Covid-19) diseases. Promising clinical results were obtained in the treatment of sarcopenia in an international phase 2 study, enabling the launch of a phase 3 study in this indication (SARA project). The safety and efficacy of Sarconeos (BIO101) in the treatment of severe COVID-19 were studied in a positive international phase 2-3 clinical trial (COVA project). A pediatric formulation of Sarconeos (BIO101) is currently being developed for the treatment of Duchenne Muscular Dystrophy (DMD, MYODA project). 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 ADSs (American Depositary Shares) are listed on Nasdaq Capital Market (Ticker BPTS - ISIN: US09076G1040).
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. 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 "Risk and uncertainties the Company is to face» section from the Company's 2022 Financial Report available on BIOPHYTIS website (www.biophytis.com) and as exposed in the "Risk 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.

Biophytis contacts

Investor relations

Nicolas Fellmann, CFO
Investors@biophytis.com

Media

Antoine Denry: antoine.denry@taddeo.fr – +33 6 18 07 83 27
Nizar Berrada: nizar.berrada@taddeo.fr – +33 6 38 31 90 50