

Biophytis to evaluate BIO101's potential to limit weight regain in its OBA clinical study in obesity

- **Regulatory protocol amendment filed in Brazil, with submissions planned in the United States and Europe**
- **"Rebound effect": expansion of the scope of BIO101 evaluation following semaglutide discontinuation**
- **A new follow-up phase to assess weight regain and the role of BIO101**

Paris (France) and Cambridge (Massachusetts, U.S.), September 9, 2026, at 07:00am CET – Biophytis SA (Euronext Growth Paris: ALBPS), ("**Biophytis**" or the "**Company**"), a pioneering company in the development of transformative therapies impacting longevity, today announces that it has submitted to the Brazilian Health Regulatory Agency (ANVISA) an amendment to the protocol of the phase 2 OBA clinical study in obesity.

This protocol amendment includes the evaluation of BIO101's potential to limit weight regain, or "rebound effect," observed after discontinuation of treatment with semaglutide, a GLP-1 receptor agonist. Submission of the same amendment to the U.S. Food and Drug Administration (FDA) is expected in the coming days.

This new evaluation complements the initial objective of the OBA study, which is to measure the effect of BIO101 on muscle function and mobility in obese or overweight patients treated with a GLP-1 agonist. In particular, the study aims to determine whether BIO101 can preserve lower-limb muscle strength during semaglutide-induced weight loss.

A new dimension in the evaluation of BIO101

The amended protocol provides for the evaluation of the rebound effect under BIO101 following discontinuation of the 21-week semaglutide treatment. While GLP-1 receptor agonist-based treatments enable significant weight loss, their discontinuation may be followed by weight regain. The addition of an evaluation period therefore addresses an important clinical issue for patients treated with semaglutide.

The follow-up period added to the OBA study protocol, which follows semaglutide treatment, extends over 12 weeks: it will make it possible to characterize any weight regain and to explore the role of BIO101 in maintaining the benefits achieved during the semaglutide treatment phase. Preventing or reducing this rebound effect represents a new therapeutic opportunity for BIO101, complementing its potential in preserving muscle mass, strength, and mobility.

Stanislas Veillet, Chairman and Chief Executive Officer of Biophytis, stated: "*The submission of this amendment to ANVISA marks an important new step in the development of BIO101 in obesity. Evaluating the period following semaglutide discontinuation will allow us to explore a major clinical issue: weight regain after discontinuation of treatment with a GLP-1 receptor agonist. With this new dimension, the OBA study could provide data on the potential of BIO101 both during weight loss and during the rebound period. We plan to submit the same protocol to the FDA in the coming days, followed by the EMA, with the goal of starting the study in the first quarter of 2027 and reporting in the first half 2028.*"

Biophytis expects to receive a response from ANVISA within an estimated regulatory timeframe of 90 days. The expected response time from the FDA is 30 days, subject to any additional requests from the authorities.

In the coming weeks, Biophytis will carry out the regulatory and operational steps necessary for the international deployment of the OBA study:

- Submission of the protocol amendment to the FDA and to the European Medicines Agency (EMA) in the coming weeks;

- Finalization of agreements with Blanver, the pharmaceutical partner, and EMBRAPPII (Farmavax), the Brazilian public agency dedicated to promoting industrial innovation, for the clinical development of BIO101 in obesity in Brazil.
- Study start, with the first patient enrolled ("First Patient First Visit"), expected in the first quarter of 2027.

About the OBA Clinical Study

The OBA study is a phase 2 clinical trial evaluating BIO101 in 164 obese and overweight patients treated with semaglutide. Conducted in the United States, Europe, and Brazil, it aims to explore the potential of BIO101 on muscle function, mobility, and certain complications associated with obesity. The study's primary endpoint is the improvement in lower-limb muscle strength, assessed by the knee extension test. The amended protocol also provides for an evaluation of weight regain beyond the 21 weeks of semaglutide treatment, over an additional 12-week period.

By combining BIO101 with GLP-1 treatment, Biophytis aims to explore an approach designed to preserve muscle strength and mobility during weight loss, while also evaluating BIO101's potential to limit weight regain after semaglutide discontinuation. The study is part of the licensing agreement entered into with Blanver, one of the leading pharmaceutical companies in Brazil and Latin America, with a presence notably in Brazil, Mexico, Argentina, and Colombia. Under the terms of this partnership, Biophytis could receive up to €108 million, including an upfront payment and additional payments contingent on the achievement of certain milestones. Biophytis is also eligible to receive double-digit royalties on net sales in the relevant territory, following the receipt of future marketing authorizations. Biophytis further benefits from non-dilutive financial support from EMBRAPPII, the Brazilian public agency dedicated to industrial innovation.

About BIOPHYTIS

Biophytis SA is a clinical-stage biotechnology company focused on developing drug candidates for age-related diseases. BIO101 (20-hydroxyecdysone), our lead drug candidate, is a small molecule in development for muscular diseases (sarcopenia, Phase 3 ready to start) and metabolic disorders (obesity, Phase 2 ready to start). The company is headquartered in Paris, France, with subsidiaries in Cambridge, Massachusetts, USA, and Brazil. The Company's ordinary shares are listed on Euronext Growth Paris (ALBPS - FR001400OLP5) and its ADS (American Depositary Shares) are listed on the OTC market (BPTSY - US 09076G401). 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 2023 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 because of new information or otherwise, except as required by law.

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