

## Biophytis announces the design of its phase 2 OBA clinical study in obesity

Paris (France) and Cambridge (Massachusetts, USA), May 14, 2024 – 07:00 am CET – Biophytis SA (Euronext Growth Paris : ALBPS), ("Biophytis" or the "Company"), a clinical-stage biotechnology company specialized in the development of therapeutics for age-related diseases, today announces the design of its phase 2 OBA clinical study in obesity with BIO101 (20-hydroxyecdysone).

BIO101 (20-hydroxyecdysone) will be evaluated in obese patients treated with GLP-1 RAs, together with hypocaloric dieting. The OBA phase 2 study will test the efficacy and safety of BIO101 (20-hydroxyecdysone) in patients with obesity and overweight with secondary comorbidities, who are starting treatment with GLP-1 RAs for weight loss.

Stanislas Veillet, CEO of Biophytis, stated: *"It is crucial for Biophytis to position itself on this gigantic medical challenge which also presents a great potential market. We believe BIO101 (20-hydroxyecdysone) has the potential to be the molecule of choice for preserving muscle function in patients suffering from obesity who are treated for weight loss with GLP-1 RAs. We are confident that our drug candidate, subject to regulatory approvals, could enter into a phase 2 clinical trial mid 2024 and that first results could be reported in 2025"*.

The OBA Phase 2 study is a double-blind, randomized, placebo-controlled clinical study in which 164 patients are planned to be enrolled with obesity (BMI  $\geq 30$ ) or overweight (BMI  $\geq 27$  with one or more sequelae e.g. diabetes, hypertension) at the start of treatment with GLP-1 RAs in combination with hypocaloric diet. Double-blind treatment with 350 mg BID of BIO101 (20-hydroxyecdysone) will be given for 21 weeks.

The primary efficacy endpoint is muscle strength as measured by knee extension, and important secondary outcomes include 6 Minute Walking Distance and other performance tests, muscle strength normalized to lean body mass, appendicular lean mass and fat mass, biomarkers and various Patient-Reported Outcomes (PROs).

Biophytis is preparing for filing an Investigational New Drug (IND) to start the OBA Phase 2 study in the USA in the coming weeks.

The OBA Phase 2 clinical study is expected to start mid 2024, upon regulatory approvals, with first patients expected to be treated in the second half of 2024.

First results of the safety and efficacy of BIO101 (20-hydroxyecdysone) drug candidate are expected to be available in 2025.

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## **About BIOPHYTIS**

Biophytis SA is a clinical-stage biotechnology company specializing in the development of drug candidates for age-related diseases. BIO101 (20-hydroxyecdysone), our lead drug candidate, is a small molecule in development for muscular (sarcopenia, phase 3 ready and Duchenne muscular dystrophy), respiratory (Covid-19 phase 2-3 completed) and metabolic diseases (obesity, phase 2 to be started). 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 OTC market (Ticker: BPTSY – ISIN: US09076G4010). For more information, visit [www.biophytis.com](http://www.biophytis.com)

## **Forward-looking statements**

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](http://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.

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