

Biophytis launches OBA phase 2 clinical study in obesity with BIO101 (20-hydroxyecdysone)

Promising preclinical results obtained in obesity support the OBA Phase 2 clinical study expected to start mid-2024

Paris (France) and Cambridge (Massachusetts, USA), April 08, 2024 – 11:00pm CET – Biophytis SA (Nasdaq CM : BPTS, 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 that it is launching a new clinical development program named OBA, with BIO101 (20-hydroxyecdysone) as a potential treatment for obesity in combination with GLP-1 receptor agonists.

Muscle loss due to obesity treatment: no therapy available today

Obesity treatment can lead to loss of muscle mass and function, notably as a consequence of dieting when combined with the recently introduced GLP-1 receptor agonists. Glucagon-like peptide-1 receptor agonist (GLP-1 RA) drugs are very effective drugs that lead to significant weight loss. Up to 40% of the total weight loss comes from muscle, which is a problem as muscle tissue's role is central in controlling metabolism, on top of its motor function.

More than 15 million adults in the US will be treated with an anti-obesity medication by 2030, representing 13% penetration into the US adult population. With an estimated market size of \$6 billion in 2023 and an estimated average annual growth rate expected around 42%, the addressable market for the treatment of obesity is set to reach \$100 billion by 2030 (*source: Goldman Sachs Research*).

Promising results already obtained in obesity

BIO101 (20-hydroxyecdysone) is the first oral daily MAS receptor activator and has demonstrated metabolic effects on muscle and fat tissues in preclinical studies in obesity. These beneficial effects of BIO101 (20-hydroxyecdysone) may translate into improved mobility and muscle strength in obese sarcopenic patients, as suggested in the SARA-INT phase 2 study. Furthermore, the 20-hydroxyecdysone molecule was already tested in obese patients during hypocaloric dieting in the Quinolita study, showing promising effects on muscle strength and fat mass loss. BIO101's (20-hydroxyecdysone) potential in the treatment of obesity in combination with GLP-1RAs to counteract the undesirable effects on muscle wasting associated with drastic weight-loss was highlighted in [Nature Biotechnology](#) ("*After obesity drugs' success, companies rush to preserve skeletal muscle*") on March 05, 2024.

Stanislas Veillet, CEO of Biophytis, stated: "*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 with GLP-1 RAs. Our drug candidate, subject to regulatory approvals, could contribute to meeting crucial medical challenges, while positioning Biophytis in a large market with incredibly high growth potential. We believe that our leadership in developing drugs for muscular diseases and promising results obtained in obesity will be a strong accelerator of the OBA clinical plan.*"

An accelerated clinical development with results expected in 2025

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. BIO101 (20-hydroxyecdysone) will be evaluated in obese patients treated with GLP-1 RAs, and following hypocaloric dieting. We expect the first results of the efficacy of our drug candidate to be available in 2025. Further information on the OBA program and the clinical study is expected to be provided through the coming weeks.

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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 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 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 as a result of new information, future developments or otherwise, except as required by law.

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