Press release

Biophytis showcased the OBA program in obesity at the 17th SCWD international congress

Paris (France) and Cambridge (Massachusetts, USA), December 23, 2024 - 07:00 - Biophytis SA (Euronext Growth Paris: ALBPS; Nasdaq CM: BPTS), the clinical-stage biotechnology company specializing in the development of treatments for age-related diseases, took part in the 17th international SCWD (*Society on Sarcopenia, Cachexia & Wasting disorders*) congress, a flagship event bringing together experts from around the world to share innovations on sarcopenia, cachexia and muscle wasting including weight loss induced muscle disorders. At this occasion, Rob van Maanen, *Chief Medical Officer* of Biophytis, presented the OBA clinical development program with BIO101 (20-hydroxyecdysone), our drug candidate to reduce GLP-1RA-induced muscle mass or function loss in patients with obesity or overweight.

The clinical profile of BIO101 in obesity was presented by Rob van Maanen, *Chief Medical Officer* of Biophytis, in a presentation titled **"BIO101 + GLP-1 RA to Prevent Potential Muscle Loss in Overweight and Obese Patients"**. Results from the Quinolia clinical study in overweight and obese patients following a hypocaloric diet and treated with 20-hydroxyecdysone (20E) were shared, demonstrating on the secondary parameters a reduction in fat mass and a trend for a promising effect of 20-hydroxyecdysone on muscle strength (maintenance of strength). Additionally, an analysis of the sarcopenic obese patient subgroup from the phase 2 study (SARA-INT) in sarcopenia suggests a possible effect of BIO101 (20-hydroxyecdysone) on muscle function, with a nominally statistically significant improvement observed in this subgroup in the 400-meter walking speed test.

These findings support the continued clinical development of BIO101 in obesity, with plans to initiate the phase 2 OBA study in 2025. This study aims to evaluate the efficacy and safety of BIO101 in obese patients treated with GLP-1 RAs (Semaglutide or Wegovy).

Stanislas Veillet, CEO of Biophytis, states : *"This is the first time that Biophytis has presented its results in obesity at an international congress such as the SCWD. These results are very encouraging and confirm our determination to focus our clinical development strategy on our drug candidate BIO101* (20-hydroxyecdysone). *These results will also enable us to launch the* phase 2 OBA clinical trial in obesity *in early 2025."*

Results of the Quinolia clinical study.

The Quinolia (QE) study is a double-blind, placebo-controlled clinical trial involving 58 overweight and obese adults treated with a low dose of 37.5 mg/day of 20E over a 6-week hypocaloric diet period followed by a 6-week maintenance diet phase. The reduction in android fat mass and adipocyte diameter was nominally significantly greater in the 20E group compared to the placebo group. Moreover, in the subgroup of patients who lost at least 5% of their body weight, muscle strength (measured by hand grip strength) was maintained in the 20E group, whereas it declined in the placebo group, although this difference did not reach statistical significance ($p = 0.09$). These effects were observed despite the low dose of 20E used (20 times lower than the dose planned for the phase 2 OBA study) and the relatively small number of treated patients. This initial proof-of-concept study is highly encouraging and supports Biophytis in advancing to phase 2 of its OBA clinical trial.

Phase 2 OBA Study in Obese Patients Treated with a GLP-1 RA (Semaglutide or Wegovy)

The phase 2 OBA study is a double-blind, randomized, placebo-controlled clinical trial that will recruit 164 patients with obesity (BMI ≥30) or overweight (BMI ≥27 with one or more comorbidities such as hypertension) at the initiation of GLP-1 RA therapy combined with a hypocaloric diet. Double-blind treatment with 350 mg BID of BIO101 (20-hydroxyecdysone) will be administered over a 21-week period.

The primary efficacy endpoint is muscle strength, measured by knee extension. Secondary endpoints include the 6-minute walk distance and other performance tests, muscle strength normalized to lean mass, appendicular lean mass, fat mass, biomarkers, and various patient-reported outcomes (PROs).

The principal investigator is Marc-André Cornier, Professor of Medicine at the University of South Carolina and President of the American Obesity Society.

The phase 2 OBA clinical trial is expected to begin in the first half of 2025, pending final regulatory approvals for the opening of the eight planned clinical centers in the United States and Europe, subject to the company's financial resources.

Initial results on the safety and efficacy of the drug candidate BIO101 (20-hydroxyecdysone) are anticipated by late 2025 at the earliest.

The presentation and posters are available on the Biophytis website:
https://www.biophytis.com/fr/aging-sciences/sarcopenie/publications-posters-muscular-disease/posters-2024/

* * * *

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 to go, and Duchenne muscular dystrophy, phase 1-2 to go), respiratory (Covid- 19, phase 2-3 complete) and metabolic (obesity, phase 2 to go) diseases. 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 ADSs (American Depositary Shares) are listed on the OTC market (BPTSY - US 09076G401). For further information, visit www.biophytis.com.

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 using 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. These forward-looking statements are based on assumptions that Biophytis considers reasonable. However, there can be no assurance that the statements contained in these forward-looking statements will prove to be correct, as they are subject to various risks and uncertainties. The forward-looking statements contained in this press

release are also subject to risks not presently known to Biophytis or that Biophytis currently deems immaterial. Consequently, there are or will be important factors that could cause actual results to differ materially from those indicated in such statements. Please also refer to the "Risks and Uncertainties Facing the Company" section of the company's 2023 Annual Financial Report available on the BIOPHYTIS website (www.biophytis.com) and as set forth in the "Risk Factors" section of Form 20-F and other forms filed with the SEC (Securities and Exchange Commission, USA). We undertake no obligation to publicly update or revise any forward-looking statements, whether as a result of new information, future developments or otherwise, except as required by law.

Contact for investor inquiries:
Investors@biophytis.com

Media contact :
Antoine Denry : antoine.denry@taddeo.fr - +33 6 18 07 83 27
Inès de Mandiargues : ines.demandiargues@taddeo.fr - +33 6 16 16 51 78