Biophytis

Press release

Biophytis unveils Phase 2 Obesity Trial Strategy with BIO101 in Europe and Brazil

Paris, France, Cambridge (Massachusetts, United States), September 1st, 2025 – 7:00 a.m. CET – Biophytis SA ("the Company"), a pioneer in the development of transformative therapies for obesity, sarcopenia, and longevity, today provides a detailed update on its clinical and regulatory plan for the Phase 2 OBA trial of BIO101, targeting muscle wasting associated with obesity. This new program underscores Biophytis's ambition to broaden the potential of its lead candidate BIO101 into high-prevalence global indications, opening significant new value-creation opportunities for the Company and its shareholders.

Phase 2 OBA Clinical Trial Design

The OBA Phase 2 trial will be a randomized, double-blind, placebo-controlled study recruiting 164 patients across two key geographies, strategically selected to accelerate development:

- Brazil: 122 patients – providing rapid recruitment potential in a large target population,
- Europe: 42 patients – enabling early interaction with European regulators and positioning BIO101 for future EU filings.

These geographies were strategically selected to balance rapid recruitment capabilities in Brazil's large population base (where Biophytis has already signed an exclusive license agreement with Blanver for Latin America) with early regulatory engagement in Europe, ensuring a robust, global dataset to support future registration efforts.

Strategic Rationale and Business Opportunity

- Obesity prevalence: Over 1 billion people worldwide are obese today, including ~150 million adults in Europe and nearly 70 million in Brazil.
- Muscle wasting in obesity (sarcopenic obesity) affects an estimated up to 40% of obese individuals, translating into a several tens of millions of patients across target regions.
- Direct healthcare costs associated with obesity and related functional decline exceed hundreds of billions of euros annually across OECD countries, with muscle wasting and loss of mobility emerging as major cost and disability drivers.

By focusing BIO101 on this intersection of metabolic and muscular health, Biophytis is positioning itself in a first-in-class therapeutic field, with potential addressable markets estimated in the multi-billion-euro range globally.

"*BIO101 has already demonstrated its potential in age-related sarcopenia, and we now see the opportunity to extend its benefits to the vast, underserved population of obese patients suffering from muscle decline*," said Stanislas Veillet, President and CEO. "*This trial not only expands our therapeutic horizons but also significantly enhances the commercial prospects of BIO101*."

Next Development and Investor Milestones

Biophytis is focused on advancing quickly toward trial initiation, with key steps including:

- Regulatory approvals: Completion of trial authorization processes in Europe (EMA CTA) and Brazil (IND with ANVISA),

- Site selection and activation: Finalizing agreements with leading clinical centers in both regions to accelerate patient recruitment,

- Funding strategy: Leveraging a diversified model including non-dilutive public financing programs, in combination with private and institutional capital.

These milestones are expected to generate upcoming value catalysts, as Biophytis expands its addressable markets and establishes BIO101 as a potential first-in-class therapy for muscle wasting in obesity.

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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.

Biophytis Contacts

Investor Relations
Investors@biophytis.com

US Investors
Pascal Nigen – Alpha Bronze
pnigen@alphabronzellc.com

Media contacts
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