

Biophytis unveils Phase 3 Sarcopenia Trial Strategy with BIO101 in Europe and Asia

Paris (France) and Cambridge (Massachusetts, USA), Sept 11th 2025 – 7:00 AM (CET) – Biophytis SA (Euronext Growth Paris: ALBPS), ("Biophytis" or the "Company"), a clinical-stage biotechnology company specializing in developing treatments for age-related diseases, today provides a detailed update on its clinical and regulatory plan for the Phase 3 SARA trial of BIO101, targeting age related sarcopenia. This trial is designed to be the first phase 3 ever conducted in sarcopenia, reflecting the medical need in rapidly aging populations worldwide.

Phase 3 SARA Clinical Trial Design

The SARA Phase 3 trial plan to recruit a total of 932 patients and Biophytis proposes to recruit sarcopenic patients mainly in Asia (China and Japan) and in Europe.

These regions were selected both for the magnitude of clinical need and the significant commercial potential they represent, with China and Japan ranking among the fastest-aging countries worldwide.

Commercial Opportunity

Sarcopenia represents a substantial unmet medical need and commercial market. Biophytis estimates that its initial target markets span more than 65 million patients:

- Over 36 million people are suffering from sarcopenia in China
- More than 8 million patients in Japan
- Approximately 20 million patients in Europe

With no approved drugs currently available, BIO101 has the potential to capture first-to-market leadership and become the gold standard therapy in a therapeutic area expected to grow significantly as populations age.

Financing and Partnerships

The financing of the SARA Phase 3 program will be achieved through collaborations with regional pharmaceutical companies and local investors in Asia, providing capital support while strengthening Biophytis' entry into these high-value markets. Partnerships are designed to maximize commercialization rights and reduce global development costs, aligning Biophytis with strong local players for market access and scalability.

Next Development and Investor Milestones

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

- Europe: With regulatory authorization completed, site activation and patient enrollment are set to begin in the coming months.
- China and Japan: Regulatory filings are underway, with formal trial initiation expected in 2026 once partnerships are finalized.
- Funding strategy: Leveraging a robust alliance model including non-dilutive private financing stakeholders located in China and Southeast Asia.

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

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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