Press release

Biophytis Receives EMA and Belgian Regulatory Approval to Initiate Phase 3 Sarcopenia Clinical Trial

Paris, France, Cambridge (Massachusetts, United States), August 28, 2025 – 7:00 a.m. CET – Biophytis SA ("the Company"), a pioneer in the development of transformative therapies for obesity, sarcopenia, and longevity, today announced that both Part I (European Medicines Agency scientific review) and Part II (Belgian national ethical assessment) of its Clinical Trial Application (CTA) for a Phase 3 study in sarcopenia have been successfully reviewed and accepted.

With these approvals, Biophytis is now authorized to initiate patient enrollment for the Phase 3 sarcopenia trial at selected sites in Belgium. The company will also collaborate with leading clinical centers across additional European Member States under the harmonized European framework.

"We are delighted to achieve both EMA and Belgian regulatory clearance for our pivotal Phase 3 sarcopenia trial," said Stanislas Veillet, Chief Executive Officer of Biophytis. *"This marks a significant milestone in our commitment to bringing effective therapies to those suffering from muscle loss due to aging."*

EMA Part I: Scientific & Methodological Approval
The European Medicines Agency (EMA) has completed its comprehensive Part I evaluation, confirming that the Phase 3 sarcopenia trial meets all requirements for clinical and scientific rigor. The assessment included a detailed review of the study protocol, benefit-risk profile, product quality, and supporting documentation, affirming the scientific validity and safety of the proposed research.

Part II in Belgium: National Ethical Acceptance
Concurrently, Belgian authorities have concluded their Part II review, approving all national and ethical aspects of the study. This includes local considerations such as informed consent procedures, data protection, investigator qualifications, and safeguards for participant wellbeing. The approval ensures that the trial will be conducted in compliance with Belgian regulations and to the highest ethical standards.

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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.

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