Biophytis

**Press release**

# Biophytis obtains EMA authorization to launch its Phase 2 clinical trial in obesity

**Paris, France, Cambridge (Massachusetts, United States), September 3rd, 2025 – 7:00 a.m. CET** – Biophytis SA ("the Company"), a pioneer in the development of transformative therapies for obesity, sarcopenia, and longevity, today announces that the European Medicines Agency (EMA) has issued a favorable outcome on Part I of its Clinical Trial Application (CTA) for the initiation of a Phase 2 clinical trial of BIO101 (20-hydroxyecdysone) in patients suffering from muscle wasting associated with obesity (OBA study).

This milestone represents a crucial regulatory step in advancing Biophytis' clinical development strategy within Europe. The favorable review of the scientific dossier (Part I) confirms the quality, safety, and preclinical/clinical data package supporting the initiation of the trial. Pending completion of Part II reviews at the national level by Ethics Committees, Biophytis expects to initiate patient recruitment in the coming months in Europe.

Stanislas Veillet, Chief Executive Officer of Biophytis, commented:

"*We are very pleased with the EMA's positive outcome on our CTA submission, which marks an important regulatory validation of our program. Muscle wasting in patients with obesity is an underrecognized but serious condition that substantially contributes to long-term disability and healthcare burden. Advancing BIO101 into Phase 2 clinical testing in Europe is a major step toward addressing this critical unmet medical need*."

**Next Development**

With Part I approval secured, Biophytis will now proceed with Part II submissions to national Competent Authorities and Ethics Committees in Europe. In parallel, Biophytis is actively pursuing its global regulatory strategy for BIO101. Following prior interactions with ANVISA, the Brazilian Health Regulatory Agency, the Company is preparing a registration dossier to support the initiation of the trial in Brazil.

**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