

Biophytis announces filing of an IND application with the US FDA for its phase 2 study in obesity

Paris (France) and Cambridge (Massachusetts, USA), June 10, 2024 – 07:00 am CET – Biophytis SA (Euronext Growth Paris : ALBPS), ("Biophytis" or the "Company"), a clinical-stage biotechnology company specialized in the development of therapeutics for age-related diseases, today announces that it has submitted an Investigational New Drug (IND) application with the U.S. Food and Drug Administration (FDA) regarding its phase 2 OBA clinical study in obesity with BIO101 (20-hydroxyecdysone).

The OBA study will assess the efficacy and safety of BIO101 (20-hydroxyecdysone) in patients with obesity and overweight patients with secondary comorbidities, treated for 21 weeks with GLP-1 receptor agonists (GLP-1 RAs) and undergoing hypocaloric dieting. The primary objective of the study is to assess improvements in muscle strength of lower limbs as measured by knee extension. Multiple secondary endpoints will also be explored such as mobility (as measured by the 6-minute walk test) and body composition (fat mass, lean body mass). This placebo-controlled multicenter international study is expected to start mid-2024, following regulatory approval to be received from the FDA no sooner than 30 days after the filing, with first patients expected to be treated in the second half of 2024. Biophytis is also actively engaging in the process to broaden its research capacity by including European clinical centers. First results of the efficacy of BIO101 (20-hydroxyecdysone) are expected in 2025.

The principal investigator will be Professor Marc-André Cornier, Professor of Medicine and Director of the Division of Endocrinology, Diabetes and Metabolic Diseases at the Medical University of South Carolina. He is a worldwide recognized medical expert in the field of obesity and is currently President-Elect of the US-based Obesity Society. Professor Cornier has joined Biophytis' Scientific Advisory Board for the OBA project, already composed of Professor Dennis Villareal and Professor Francisco Guarner.

Stanislas Veillet, CEO of Biophytis, stated: *"More than 15 million adults in the US will be treated with anti-obesity medications by 2030, representing 13% penetration into the US adult population and an estimated addressable market size of \$100 billion. It is crucial for Biophytis to position itself on this gigantic medical challenge which also presents great potential revenue. The filing of the Investigational New Drug application shows our commitment to accelerate our development in this indication and should be attractive to potential pharma partners."*

Professor Cornier is currently Professor of Medicine and Director of the Division of Endocrinology, Diabetes and Metabolic Diseases at the Medical University of South Carolina. Prior to that he was on faculty at the University of Colorado with the Division of Endocrinology, Metabolism and Diabetes until 2021.

At the University of Colorado, Dr. Cornier was the Associated Division Head for Endocrinology as well as the Associate Director and Medical Director of the University of Colorado Anschutz Health and Wellness Center. Dr. Cornier was also on staff at Denver Health Medical Center in Denver, Colorado from 1999 to 2016 as a general clinical endocrinologist and at Aspen Valley Hospital in Aspen, Colorado from 2017 to 2021.

Dr. Cornier is an active clinical and translational investigator with a primary research interest in understanding the complex regulation of food intake and body weight and in studying optimal interventions for weight management and metabolic health. He has also been involved in clinical trials for investigational treatments for lipid disorders and obesity. Dr. Cornier has been an active volunteer in important health-



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related associations, such as the Endocrine Society, American Diabetes Association, American Heart Association, National Lipid Association, and The Obesity Society.

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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 and Duchenne muscular dystrophy), respiratory (Covid-19 phase 2-3 completed) and metabolic diseases (obesity, phase 2 to be started). The company is based in Paris, France, and Cambridge, Massachusetts. The Company's ordinary shares are listed on Euronext Growth (Ticker: ALBPS -ISIN: FR0012816825) and the ADSs (American Depositary Shares) are listed on OTC market (Ticker: BPTSY – ISIN: US09076G4010). For more information, visit www.biophytis.com

Forward-looking statements

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 as a result of new information, future developments or otherwise, except as required by law.

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