

Press release

# **BIOPHYTIS** launches the second phase of Sarconeos pharmacokinetics study (SARA-PK) after successful completion of the initial phase

Sarconeos, BIOPHYTIS' lead product candidate intended for sarcopenia, safe and well-tolerated in first portion of pharmacokinetics study

Romainville, September 22<sup>nd</sup> 2016, 7:30 am – BIOPHYTIS (Alternext Paris: ALBPS), a biotechnology company specialized in the development of drug candidates to treat ageing diseases, announces the successful completion of the SARA-PK SAD (Single Ascending Dose) portion of a pharmacokinetics (PK) study for its lead product, Sarconeos, being developed to treat sarcopenia.

The objective of the SARA-PK study is to assess the safety, tolerability and pharmacokinetic profile of Sarconeos in elderly healthy volunteers (> 65 years old). The study is being conducted in two phases: single ascending dose (SAD) administration and multiple ascending dose (MAD) administration.

The recently completed SAD portion of the study was aimed at comparing pharmacokinetics in elderly and young volunteers following escalating single dose administrations. No severe adverse event related to Sarconeos were reported following any of the four administered doses, ranging from 100 mg/day up to 1400 mg/day, in 24 young or old subjects enrolled.

The SARA-PK MAD portion of the study is beginning now and will evaluate the safety and pharmacokinetics of Sarconeos in 30 older subjects, following multiple ascending oral administrations daily for 10 days. Data from the second portion of the study will be reported by the end of the year and will be used to select the two doses of Sarconeos for study in the Phase 2b SARA-INT trial, which is currently expected to begin in the first half of 2017.

**Stanislas Veillet, Chief Executive Officer of BIOPHYTIS, says:** "We are pleased with the SAD study results which demonstrated that Sarconeos was safe and well-tolerated among both young and older volunteers. These positive results enable us to begin the MAD portion of the PK study, which we anticipate will be completed prior to year-end and, if successful, will enable us to initiate the SARA international Phase 2b trial in the first half of 2017."

#### **About SARCONEOS:**

Sarconeos is the first representative of a new class of drug candidates, based on the activation of the MAS receptor (major player of the renin-angiotensin system) stimulating anabolism in the muscle, inhibitor of myostatin and favoring muscle mass development in animal models of muscular

dystrophies. Sarconeos is developed in the treatment of sarcopenia, an age-related degeneration of skeletal muscle and strength, leading to a loss of mobility in elderly people. This new pathology, for which no medical treatment currently exists, was first described in 1993 and just entered the WHO International Classification of Diseases (M62.84), affects more than 50 million people worldwide.

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### **About BIOPHYTIS:**

Biophytis SA (www.biophytis.com), founded in 2006, develops drug candidates targeting diseases of aging. Using its technology and know-how, Biophytis has discovered and begun clinical development of innovative therapeutics to restore the muscular and visual functions in diseases with significant unmet medical need. Specifically, the company is advancing two lead products into mid-stage clinical testing next year: Sarconeos (BIO101) to treat sarcopenic obesity and Macuneos (BIO201) to treat dry age-related macular degeneration (AMD). The company was founded in partnership with researchers at the UPMC (Pierre et Marie Curie University) and also collaborates with scientists at the Institute of Myology, and the Vision Institute.

BIOPHYTIS is listed on the Alternext market of Euronext Paris (ALBPS; ISIN: FR0012816825). For more information: <u>http://www.biophytis.com</u>

BIOPHYTIS is eligible for the Equity Saving Plans PEA-PME.





## Disclaimer

This press release contains certain forward-looking statements. Although the Company believes its expectations are based on reasonable assumptions, these forward-looking statements are subject to numerous risks and uncertainties, which could cause actual results to differ materially from those anticipated. For a discussion of risks and uncertainties which could cause the Company's actual results, financial condition, performance or achievements to differ from those contained in the forward looking statements, please refer to the Risk Factors ("Facteurs de Risque") section of the Listing Prospectus upon the admission of Company's shares for trading on the regulated market Alternext of Euronext Paris filed with the AMF, which is available on the AMF website (www.amf- france.org) or on BIOPHYTIS' website (www.biophytis.com).

This press release and the information contained herein do not constitute an offer to sell or a solicitation of an offer to buy or subscribe to shares in BIOPHYTIS in any country. Items in this press release may contain forward-looking statements involving risks and uncertainties. The Company's actual results could differ substantially from those anticipated in these statements owing to various risk factors which are described in the Company's prospectus. This press release has been prepared in 5 both French and English. In the event of any differences between the two texts, the French language version shall supersede.

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