

## Biophytis: Full results of SARA-PK study confirm Sarconeos' good pharmacokinetic profile in elderly patients

Paris (France), 1<sup>st</sup> March 2017, 18H00 - BIOPHYTIS (Alternext Paris : ALBPS), a biotechnology company specialising in the development of drug candidates to treat diseases of ageing, announces today the complete results of the SARA-PK study, in particular the favourable pharmacokinetics and pharmacodynamics of Sarconeos.

The analyses confirm the good pharmacokinetic profile in healthy elderly volunteers, the therapeutic window of Sarconeos, and confirms the dosages that will be tested in the Phase 2b trial SARA-INT. The study's complete results will be presented at the International ICFSR on April 28<sup>th</sup> in Barcelona.

**Stanislas Veillet, CEO of BIOPHYTIS, declares:** *"The analysis of the complete results of the SARA-PK trial confirms Sarconeos' good pharmacokinetic profile and allows us to determine the doses that will be tested in the Phase 2b study, SARA-INT, which we hope to start in mid-2017. These data will be used now to complete the regulatory filings required for the authorisations to start in U.S. and Europe SARA-INT, the interventional Phase 2b trial in sarcopenia patients.*

Safety data collected at the end of SARA-PK had already confirmed the good tolerability profile and the absence of any serious adverse event associated with the administration of Sarconeos. These safety results had already been presented at the 9<sup>th</sup> international conference on Cachexia, Sarcopenia and muscle Wasting Disease (SCWD) held in Berlin last December.

The complete results of the SARA-PK study, in particular the pharmacokinetic profile of the Sarconeos product, have now been analysed and top-line data are being communicated today for the first time. The main parameters of the pharmacokinetics (half-life, area under curve, maximum plasma concentration of the product, etc) have been estimated, allowing the confirmation of Sarconeos' good pharmacokinetic profile in healthy elderly volunteers, which is not significantly different from the profile observed in adult volunteers.

The qualitative study of biomarkers of muscular metabolism (creatinine kinase, myoglobin, etc) and of the renin-angiotensin system (renin, aldosterone, etc) gathered at the end of the trial, allows for the description of Sarconeos' pharmacodynamic profile. The study of Sarconeos' effects on these biomarkers in SARA-INT should allow the confirmation of these patterns.

The complete analysis of the safety, pharmacokinetic and pharmacodynamic data allows the confirmation of Sarconeos' favourable therapeutic window and the selection of the two doses which

will be tested in the placebo-controlled Phase 2b SARA-INT trial, provided it is authorized by the relevant regulatory agencies. The selected oral doses are: 175 mg twice-daily and 350mg twice-daily.

The complete results of the SARA-PK study will be presented in an oral presentation at the ICFSR (International Conference on Frailty & Sarcopenia Research) which will take place in Barcelona from April 27th to 29th of. The title of the presentation will be: “SARA-PK: A single and multiple ascending oral doses study to assess the safety and evaluate the pharmacokinetics of BIO101 in healthy young and older volunteers”. An abstract of the presentation also will be published in a special edition of the scientific review *The Journal of Frailty & Aging*.

#### About SARA-PK:

The objective of the SARA-PK study was to evaluate safety, tolerance and the pharmacokinetic profile of Sarconeos in healthy elderly volunteers (>65 years). The study was carried out in two phases: the administration of a single ascending dose (SAD), and multiple ascending doses (MAD). The second stage of the study – MAD (multiple ascending doses) – which has just been reached, had as its objective the evaluation of the safety, tolerance and pharmacokinetics of Sarconeos in subjects aged 30, after the oral administration of 3 multiple ascending doses (350mg/day, 700 mg/day then 900 mg/day) every day over 14 days. Both phases of the SARA-PK study were carried out successfully.

#### About BIOPHYTIS:

Biophytis SA ([www.biophytis.com](http://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). Located on the Pierre et Marie Curie University (UPMC) campus in Paris, BIOPHYTIS 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: <http://www.biophytis.com>

BIOPHYTIS is eligible for the SMEs scheme.



#### 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](http://www.amf-france.org)) or on BIOPHYTIS’ website ([www.biophytis.com](http://www.biophytis.com)).

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