

## Biophytis presents preliminary clinical data of SARA-PK, and new preclinical data of Sarconeos for treating sarcopenia.

Four Posters presented at 9<sup>th</sup> SCWD International Conference  
Berlin, December 10-11<sup>th</sup> 2016

Romainville (France), December 16<sup>th</sup>, 2016, 6.00pm - BIOPHYTIS (Alternext Paris: ALBPS), a biotechnology company specializing in the development of drug candidates to treat diseases of ageing, announced today that new preclinical and clinical data on Sarconeos (BIO101), the Company's lead drug candidate in the treatment of Sarcopenia, have been presented at the 9<sup>th</sup> International Conference on Sarcopenia, Cachexia and Wasting Disorders in Berlin the 10<sup>th</sup> and 11<sup>th</sup> of December in the form of four posters.

**Stanislas Veillet CEO BIOPHYTIS**, said: *"We are extremely proud to have been able to unveil this new path for the treatment of sarcopenia to the international experts gathered at the conference. The potential of our drug candidate in the treatment of sarcopenia has been demonstrated through the 4 new studies presented and confirms the value of the research conducted by Biophytis. This lays the ground for obtaining the regulatory approvals to start the Phase 2b SARA-INT mid-2017."*

Sarcopenia is defined as a loss of muscle mass and strength with ageing leading to severe decline in mobility and physical ability. Although no candidate drug has received yet marketing authorization for this geriatric condition, Sarcopenia was recently recognized as an independent geriatric condition by the International Classification of Disease (WHO).

Various experiments in human and mice myocytes<sup>1</sup> demonstrated that the anabolic effects of Sarconeos in skeletal muscles result from an activation of Mas receptor, the receptor of Angiotensin 1-7, a key component of the Renin-Angiotensin system, followed by the activation of AKT/mTOR, MAPK and AMPK pathways leading to the inhibition of myostatin gene expression.

A new study<sup>2</sup> in ageing mice demonstrated the potential of Sarconeos in improving skeletal muscle quality and in compensating the significant loss of mobility, as a consequence of ageing. An other study led in young mice submitted to chronic oral administration of Sarconeos, demonstrated higher protein content and a significant reduction of myostatin gene expression in skeletal muscles.

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<sup>1</sup> Mechanism of action of BIO101, a Mas receptor activator: A drug candidate for the treatment of sarcopenia. *Journal of Cachexia, Sarcopenia and Muscle*, vol.7 (issue 5), December 2016, pages 655-656. Abstract 4-02.

<sup>2</sup> BIO101, a drug candidate targeting Mas receptor for the treatment of age-related muscle degeneration. From molecular target identification to clinical development. *Journal of Cachexia, Sarcopenia and Muscle*, vol.7 (issue 5), December 2016, pages 655. Abstract 4-01.

A safety and pharmacokinetic study (SARA-PK)<sup>3</sup> completed in H2 2016 in adult and elderly volunteers (> 65 years old) confirmed the good safety profile of Sarconeos, with no severe adverse event recorded at the tested doses (up to 1400 mg/day). The pharmacokinetic profile is not significantly different between old and adults volunteers. Moreover, no food effect has been detected. The complete results of the SARA-PK study will be available Q1 2017 and used for filing regulatory approvals in Europe and the US of the Phase 2b SARA-INT trial.

An observational clinical study (SARA-OBS)<sup>4</sup> just started, with the objective of assessing the 6-month rate of change in mobility, muscle strength, and muscle mass, of 300 participants in 8 centers in Europe and the USA. The patients could be later recruited in the phase 2b SARA-INT study. As Regulatory experts in Europe and the USA do insist on the importance of testing Patient Reported Outcomes aside standard measurements to demonstrate clinical efficacy, Electronically administered Patient Reported Outcome (ePROs), via remotely connected devices, are now being tested in SARA-OBS, with the potential to be later used in the phase 2b SARA-INT.

**Conference abstracts:**

<http://www.jcsm.info/index.php/en/volume-7-number-5-december-2016>

1. Serova M., Raynal S., On S., Veillet S., Diah W., Dilda P.J., Lafont R.: Mechanism of action of BIO101, a Mas receptor activator: A drug candidate for the treatment of sarcopenia. Journal of Cachexia, Sarcopenia and Muscle, vol.7 (issue 5), December 2016, pages 655-656. Abstract 4-02.
2. Dilda P.J., Foucault A.S., Serova M., On S., Raynal S., Veillet S., Diah W., Lafont R. : BIO101, a drug candidate targeting Mas Receptor for the treatment of age-related muscle degeneration. From molecular target identification to clinical development. Journal of Cachexia, Sarcopenia and Muscle, vol.7 (issue 5), December 2016, pages 655. Abstract 4-01.
3. Diah W., Del Signore S., Dupont P., Daudigny L., Veillet S.: SARA-PK: A combined study of the safety and pharmacokinetics of BIO101 in healthy young and older volunteers after single ascending and multiple ascending oral doses for 14 days. Journal of Cachexia, Sarcopenia and Muscle, vol.7 (issue 5), December 2016, pages 656-657. Abstract 5-01.
4. Del Signore S., Zia G., Del Signore St., Diah W.: Electronically administered Patient Reported Outcomes (ePROs) in sarcopenic older patients – the SARA Clinical data Platform novel approach to Clinical Trials. Journal of Cachexia, Sarcopenia and Muscle, in press.

**About The Society on Sarcopenia, Cachexia, and Wasting Disorders (SCWD)**

The Society on Sarcopenia, Cachexia and Wasting Disorders was founded in 2008 on the initiative of Dr. Stefan D. Anker and Dr. John E. Morley, whose leadership and vision guided the expansion of clinical

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<sup>3</sup> SARA-PK: A combined study of the safety and pharmacokinetics of BIO101 in healthy young and older volunteers after single ascending and multiple ascending oral doses for 14 days. *Journal of Cachexia, Sarcopenia and Muscle*, vol.7 (issue 5), December 2016, pages 656-657. Abstract 5-01.

<sup>4</sup> Electronically administered Patient Reported Outcomes (ePROs) in sarcopenic older patients – the SARA Clinical data Platform novel approach to Clinical Trials. *Journal of Cachexia, Sarcopenia and Muscle*, in press.

expertise and research in this field. The Society on Sarcopenia, Cachexia and Wasting Disorders is a non-profit scientific organization comprised of an international and multidisciplinary group of health-care professionals primarily active in these fields. The SCWD seeks to further research on cachexia and sarcopenia and wasting disorders and bring practical solutions to health-care teams worldwide grappling with treatment. The spectrum of clinical disorders represented by the SCWD Society includes, but is not limited to cachexia, sarcopenia, the syndrome of muscle wasting associated to cancer, COPD, diabetes, heart failure, aging and other chronic conditions. In recent years, there has been tremendous growth in new diagnostic information, pharmacological and nutritional treatments for wasting disorders, as well as a greater number of associated clinical trials.

#### About SARCONEOS (BIO101)

Sarconeos is a first in class drug candidate based on the activation of the Mas receptor (major player of the renin-angiotensin system) restoring muscular anabolism, inhibiting myostatin that has demonstrated meaningful activity in animal models of muscular dystrophies. Sarconeos is developed in the treatment of sarcopenia, an age-related degeneration of skeletal muscle, leading to loss of mobility in elderly people. This condition, for which no medical treatment currently exists, was first described in 1993 and has entered the International Classification of Diseases (M62.84) in 2016. It affects more than 50 million people worldwide.

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#### 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 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 and 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: <http://www.biophytis.com>



#### 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)).

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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