

Biophytis filed IND application for approval by FDA of SARA-INT Phase 2b study of Sarconeos in Sarcopenia

- Protocol has been adjusted according to EMA Scientific Advice
- Filing in Europe will be done in the coming days

Paris (France), September 25, 2017, 7h45 CET – BIOPHYTIS (Euronext Growth Paris: ALBPS), a biotechnology company specializing in the development of drug candidates to treat age-related diseases, today announces that it has filed its IND application for approval by the Food and Drug Administration (FDA) in order to start in the United-States SARA-INT phase 2b interventional clinical study of Sarconeos in Sarcopenia. The protocol has been adjusted to take into consideration a scientific advice received from the European Medicines Agency (EMA). In the coming days, regulatory applications will also be filed in Europe: Belgium, France and Italy.

SARA-INT is a three-arm interventional, phase 2, randomized, double blind placebo controlled clinical trial on 334 patients, that will be conducted in 20 clinical centers (among which those participating in the SARA-OBS study), in the EU (Belgium, France and Italy) and in the USA. The protocol aims to evaluate the safety and efficacy of Sarconeos (BIO101), 175 mg b.i.d. and 350 mg b.i.d., oral administration over 6 months, to patients aged over 65 years suffering of Sarcopenia and at risk of mobility disability. The principal investigator will be Prof. Roger A. Fielding of Tufts University.

Stanislas Veillet, CEO of BIOPHYTIS, said: *“The IND application filing will be followed by submissions to the European agencies, which should lead us to first authorizations of SARA-INT during this semester. The primary endpoint: gait speed at the 400-meter walk test, has been chosen according to the recommendation of the European Medicines Agency (EMA), so that results will be comparable with the findings of benchmark studies such as the LIFE study in the USA, and on-going SPRINTT study in Europe. We have strong confidence that SARA-INT will demonstrate the benefit Sarconeos could bring to patients.”*

Hereunder are summarized the key characteristics of the protocol:

General Objectives:

1. To evaluate the safety and efficacy of two doses of BIO101 (175 mg b.i.d. and 350 mg b.i.d.) orally administered 26 weeks versus placebo in a population of community dwelling older men and women (aged \geq 65 years) at risk of mobility disability.
2. To estimate treatment effect improvement of physical function and on decrease of risk of mobility disability after six-month treatment versus placebo in the target population.

Primary Endpoint:

Gait speed measured during the 400MW test, the change from baseline to month 6 will be compared between groups of treatment (each dose versus placebo).

Key Secondary Endpoints:

Change from baseline of a standardized patient reported outcome (PRO): PF-10 subscore of the SF36; Raising from a chair (subscore of SPPB);

Other secondary Endpoints:

Change from baseline of Appendicular Lean Mass (ALM), body composition at DEXA, muscle strength (handgrip/knee extension); stair power climbing test; SPPB; 6-minute walk distance;

Study Population:

334 community dwelling older adults (men or women ≥ 65 years) reporting loss of physical function over the last six-twelve months and considered at risk of mobility disability will be included in the randomized interventional clinical trial SARA-INT (106 patients per treatment group) and will take the treatment over 26 weeks.

Main inclusion criteria:

1. Male or female, aged ≥ 65 years and living in the community, reporting loss of physical function over the last 6-12 months
2. Short Physical Performance Battery (SPPB) score ≤ 8
3. ALM/BMI < 0.789 in men and 0.512 in women, or ALM $< 19.75\text{kg}$ in men and $< 15.02\text{kg}$ in women, as measured by DEXA scan.

About SARCONEOS

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, and that had 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.

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 begun clinical development of innovative therapeutics to restore the muscular and visual functions in diseases with significant unmet medical needs. Specifically, the company is advancing two lead products into mid-stage clinical testing this year: Sarconeos (BIO101) to treat sarcopenic obesity and Macuneos (BIO201) to treat dry age-related macular degeneration (AMD).

The business model of BIOPHYTIS is to ensure the conduct of the project until clinical activity in the patient is proven, then to license the technologies in order to continue the development in partnership with a pharmaceutical laboratory.

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 Euronext Growth market of Euronext Paris (ALBPS; ISIN: FR0012816825).

For more information: <http://www.biophytis.com>

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BIOPHYTIS is eligible for the SMEs scheme



Disclaimer

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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 both French and English. In the event of any differences between the two texts, the French language version shall prevail.

BIOPHYTIS
Stanislas VEILLET
CEO
contact@biophytis.com
Tel: +33 (0) 1 41 83 66 00

Citigate Dewe Rogerson
Presse internationale & Investisseurs
Laurence BAULT/Antoine DENRY
Laurence.bault@citigate.fr
antoine.denry@citigate.fr
Tel: +33 (0)1 53 32 84 78
Mob: +33(0)6 64 12 53 61

LifeSci Advisors
Chris MAGGOS
Managing Director, Europe
chris@lifesciadvisors.com
Tel: +41 79 367 6254