

Biophytis has FAMHP Approval to conduct SARA-INT phase 2b Interventional Study of Sarconeos in Sarcopenia in Belgium

Paris (France), December 4th, 2017, 7.45am - BIOPHYTIS (Euronext Growth Paris: ALBPS), a biotechnology company specializing in the development of drug candidates to treat age-related diseases, today announces the approval from the Federal Agency for Medicines and Health Products (FAMHP) to conduct the SARA-INT phase 2b Interventional study of Sarconeos in sarcopenia in Belgium.

The FAMHP approval will enable Biophytis to initiate the SARA-INT phase 2b interventional study in 3 clinical centers in Belgium, including the University Hospital of Liège, already opened as part of the SARA-OBS observational study, with investigator Professor Olivier Bruyère.

Stanislas Veillet, CEO of BIOPHYTIS, comments: *"After receiving approval from the Food and Drug Administration (FDA) at the end of October, we are pleased to receive the approval from the FAMHP to initiate the SARA-INT interventional study in Belgium. This is another important milestone in the clinical development of our drug candidate Sarconeos in Europe. SARA-INT is the first clinical study to demonstrate the efficacy of a drug candidate on mobility in sarcopenic patients."*

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 next steps will be to obtain regulatory approvals in France and in Italy, and the inclusion of the first patients in the United States and in Europe. Patients will be notably recruited from the group of sarcopenic patients followed in the SARA-OBS study, once their consent is obtained.

About SARA-INT:

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 ≥ 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
Stanislas VEILLET
CEO
contact@biophytis.com
Tel: +33 (0) 1 44 27 23 00

Citigate Dewe Rogerson
International media & Investors
Laurence BAULT/Antoine DENRY
Laurence.bault@citigatedewerogerson.com
antoine.denry@citigatedewerogerson.com
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