biophytis
NEW THERAPEUTICS FOR AGING DISEASES

Press release

BIOPHYTIS: Inclusion of the first patient in Phase 2b Study in Sarcopenia

Preliminary results expected in Q3 2019

Paris (France), May 24, 2018, 6pm - BIOPHYTIS (Euronext Growth Paris: ALBPS), a biotechnology company specializing in the development of drug candidates to fight age-related degenerative diseases, today announces the entry and treatment of the first patient in SARA-INT, a Phase 2b clinical trial of its therapeutic-candidate Sarconeos to treat Sarcopenia. Patient recruitment is scheduled to be completed by year-end and preliminary results are scheduled during summer of 2019, with final results around the end of 2019.

Stanislas Veillet, CEO of BIOPHYTIS, said: *"The entry of the first patient into SARA-INT marks a major potential breakthrough for patients suffering from sarcopenia, a common age-related degenerative disease where there is still no available treatment despite the high risk of loss of mobility. This study will test the efficacy of Sarconeos, the first drug-candidate designed to fight loss of muscle mass and mobility in people with Sarcopenia. Recruitment has started in centers in Belgium and the United States and is scheduled to be complete by the end of the year, which will allow us to report preliminary results in summer of 2019 and final results around the end of 2019. "*

The double-blind, placebo-controlled Phase 2b SARA-INT study will include about 334 patients in 22 clinical centers in Europe (Belgium, France and Italy) and in the United States. About half of the patients will be recruited from an observational study, SARA-OBS, which has been run by Biophytis at some of the key clinical centers of SARA-INT over the past year. The other half of the patients will be recruited from 11 new clinical centers, which are in the process of opening.

The clinical protocol, in particular the inclusion criteria and the main criterion, was defined following the scientific opinion of the European Medicines Agency (EMA) and the comments of the Food & Drug Administration (FDA) in the context of a new experimental drug application (IND). In 2017, the FDA and the Belgian Medicines Agency (AFMPS) gave their agreements to start this study. Biophytis is still waiting for authorizations from French and Italian drug agencies.

The objectives of SARA-INT are to evaluate the safety and efficacy of two doses of Sarconeos (175 mg bid and 350 mg bid) administered orally for 26 weeks against placebo in a population of men and women over 65 with a risk of disability.

The SARA program's clinical strategy has been defined so that the SARA-INT study is a continuation of SARA-OBS. SARA-OBS and SARA-INT share governance, inclusion criteria, primary and secondary criteria, the SARA-DATA data management system and CRO ICON Clinical Research.

Roger Fielding, Professor at Tufts University in Boston, USA, is the principal investigator of the SARA-INT study and SARA-OBS. A Steering Committee, composed of 4 members representing the two continents participating in the study, was created for the management of these studies. The Steering Committee is chaired by the principal investigator, Professor Roger Fielding. Professor Marco Pahor (University of Florida, Gainesville, FL, USA) is vice-chair. Professors Olivier Bruyère (University of Liège, Belgium) and Yves Rolland (CHU Purpan, Toulouse, France) are the European representatives.

****

About SARA-INT

General objectives:
1. To evaluate the safety and efficacy of two doses of BIO101 (175 mg bid and 350 mg bid) given orally for 26 weeks placebo in a population of men and women over 65 years of age. years with a risk of motor disability.
2. Estimate the effect of treatment, improvement of physical function, and decreased risk of motor disability after six months of treatment with placebo in the target population.

Main evaluation criterion:
The walking speed measured during the test of 400 meters of walking, the variation compared to the baseline at the 6th month will be compared between the groups treated (each dose compared to placebo).

Main secondary endpoints:
Variation from baseline of standard Patient-Reported Outcome (PRO): PF-10 score of SF36; chair lift test (SPPB intermediate score);

Other secondary evaluation criteria:
Change in baseline of appendix body mass (ALM), body composition measured by DEXA, muscle strength (handle / knee extension); climb test of the stairs; SPPB; 6 minutes walk;

Study population:
334 individuals (male or female over 65 years) reporting a loss of physical function within the last 6-12 months and considered at risk of motor disability will be included in the SARA-INT random interventional clinical trial (106). patients per treatment group) and will take treatment over 26 weeks.

Main inclusion criteria:
1. Male or female, over the age of 65, living in the vicinity, reporting a loss of physical function in the past 6 to 12 months
2. SPPB score ≤ 8
3. ALM / BMI <0.789 in men and 0.512 in women, or ALM <19.75 kg in men and <15.02 kg in women, measured by DEXA scan.

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.
Based on the Sorbonne Université campus, Biophytis collaborates with expert scientists from several Sorbonne Université institutes such as the Paris Seine Biology Institute, 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

Follow us on Twitter @biophytis

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 Euronext Growth 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 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 44 27 23 00

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