Press release

Biophytis Provides Enrollment Update in Its Phase 2b SARA-OBS and SARA-INT Studies of Sarconeos in Sarcopenia

Over 200 patients recruited in the SARA-OBS study with the majority of patients enrolled from the U.S. and Belgium

60 patients ready to enter the SARA-INT trial

Paris (France), September 4, 2018, 7.30am - BIOPHYTIS (Euronext Growth Paris: ALBPS), a biotechnology company specializing in the development of drug candidates to fight age-related degenerative diseases, today announced that it has enrolled over 200 of the 334 sarcopenic patients in the Phase 2b SARA-OBS study in the 11 centers opened in the United States and in Europe, and that 60 patients have passed the 6-month observational phase and are now ready to enter the interventional phase of the study. The interventional study, SARA-INT, has already started in Belgium and will expand to the United States in the 11 centers already opened under SARA-OBS, as well as in the 11 new centers dedicated to SARA-INT.

Stanislas Veillet, CEO of BIOPHYTIS, said: *"The significant recruitment of Sarcopenic patients already carried out in the United States and in Belgium in our Phase 2b SARA-OBS clinical trial shows the rapid progress of the study that will allow us to test the efficacy of our drug candidate Sarconeos and validate our technology. This also marks our strong foothold in the United States, as 2/3 of the patients recruited under SARA-OBS were in the United States. Recruitment of the majority of patients in SARA-INT is expected to be completed by the end of the year, which will provide preliminary results in the second half of 2019."*

The double-blind, placebo-controlled Phase 2b SARA-INT study will include approximately 334 patients, of which more than 200 have already been recruited under SARA-OBS, which includes 11 clinical centers in Europe (Belgium, France and Italy) and in the United States. Of these more than 200 patients, 60 of them have already completed the observational study and are ready to enter the interventional study. The rest of the patients will be recruited from 11 new clinical centers, which are in the process of opening specifically for SARA-INT.

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. The agreement of the French and Italian agencies are expected to be obtained before the end of 2018.

Dr. Roger Fielding, Professor of Medicine, Tufts University of Medicine in Boston, is the Principal Investigator of the study and the Chairman of the Company's Steering Committee. Dr. Marco Pahor, Professor and Founding Chair of the Department of Aging and Geriatric Research and Director of the Institute on Aging at the College of Medicine, University of Florida in Gainesville, is Vice President of the Steering Committee. Additionally, as announced earlier, the Company recently appointed Dr. Samuel Agus as Chief Medical Officer of Biophytis, who is based in Cambridge, MA, to supervise the Company's clinical trials, especially those conducted in the US as part of the SARA study.

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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 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.
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

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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.

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