biophytis

NEW THERAPEUTICS FOR AGING DISEASES

Press Release

BIOPHYTIS unveils its clinical development strategy in the United States, as it communicates its 2015 "Document de Référence"

The Company plans to increase its investments in the United States, the largest commercial market, by developing its drug candidates Sarconeos (aka BIO101) and Macuneos (aka BIO201) in both Europe and the USA :

- **Significant increase in size of the clinical trials, SARA (for sarcopenia) and MACA (for AMD), with the recruitment of additional patients in the United States**
- **Preliminary clinical studies will be carried out with Sarconeos (SARA-PK and SARA-OBS) and with Macuneos (MACA-PK and MACA-OBS) on elderly subjects to better characterize these new indications, without marketed therapies**
- **Optimized clinical development plan will require an additional 12 to 18 months**
- **Clinical development team is strengthened with the appointment of Susanna Del Signore, MD, as Chief Medical Director**

Romainville (France), Boston (Massachusetts), March 29, 2016 – BIOPHYTIS (Alternext Paris: ALBPS), a biotechnology company specialized in the development of drug candidates to treat diseases of aging, announced today that it filed its 2015 "Document de Référence", which contains its Annual Financial Report, with the French Financial Market Authority [*Autorité des Marchés Financiers*] (AMF) today. The Company has made the following decisions:

Increasing investment in the United States, the largest commercial market. BIOPHYTIS now plans clinical development of its drug candidates in both the United States and Europe in order to (i) be in contact with the North American scientific community, and (ii) to meet FDA (Food and Drug Administration) clinical and regulatory requirements.

Significant increase in the size of both Phase 2b clinical programs, by including patients in investigation centers in the United States for both Sarconeos (formerly BIO101 for sarcopenia) and Macuneos (formerly BIO201 for dry AMD). This strategy to conduct clinical trials abroad (originally scheduled for France and Belgium only) is intended to increase the statistical power of the studies conducted and, as a result, generate more value for the company.

- **The Phase 2b SARA study** relates to a drug candidate for treatment of sarcopenic obesity : Sarconeos (formerly BIO101). BIOPHYTIS has now selected eight main clinical investigation centers in France and Belgium, where 180 sarcopenic patients will be recruited. In Europe, the Toulouse Gérontopôle will be the main center of investigation. In the United States, the Company has initiated the selection of three centers of investigation, with the principal one being Tufts University in Boston, where the goal is to recruit 120 sarcopenic patients.

  The goal of this large international clinical study will be to evaluate the effect of the Sarconeos product on the muscular function of sarcopenic persons aged over 65 years old, in accordance with criteria proposed by the Foundation for the National Institute of Health (FNIH). Two Sarconeos doses will be compared to a placebo : Sarconeos 100 mg and Sarconeos 350 mg.

  In order to conduct this international study, BIOPHYTIS has already signed a manufacturing agreement with the American company Patheon to launch production of clinical lots that will be used in the Phase 2b trial. BIOPHYTIS has already received a favorable opinion from the Federal Agency for Medicines and Products (FAMHP, the Belgian regulatory authority) on its proposed clinical development plan, which is a first step towards authorization by the relevant regulatory agencies: FAMHP (Belgium), ANSM (France), EMA (Europe), and the FDA (United States).

  Due to the extension of testing to the North American continent, the investigation phase of the SARA study, which was initially planned in the first half of 2016, will now start in the first half of 2017.

- **The Phase 2b MACA study**, relates to a drug candidate for the treatment of dry AMD : Macuneos (formerly BIO201). It is following the same clinical and regulatory development plan as Sarconeos. The investigation phase of the Phase 2b study, which will involve 300 patients, as opposed to the 180 patients initially planned, will be conducted in some 20 centers in Europe and about 10 centers in the United States.

  More specifically, the 300 subjects are to be older than 50 years old and suffer from intermediate stage dry AMD. They will be recruited in France, in at least one other European country, and in the United States, in particular at the Massachusetts Eye and Ear Infirmary at Harvard Medical School in Boston.

  The patients enrolled in the study will be divided into three groups: Macuneos 100 mg, Macuneos 350 mg, and a placebo. The investigation phase will last 18 months, with interim data reported at 9 months. It was decided to increase the number of patients with respect to the initial protocol, by adding a group of 120 patients in the United States. This increases the chance of success of the study, which is to start in the first half of 2018, versus second half of 2016 as originally planned (as soon as the regulatory authorizations are obtained).

Prior to the phase 2b trials, BIOPHYTIS will perform additional clinical studies on Sarconeos and Macuneos among elderly subjects in order to better characterize these new indications, without marketed therapies.

BIOPHYTIS has added two studies prior to the international SARA study:

- It will conduct a study in Belgium among healthy older volunteers (the SARA-PK study) in order to determine the pharamacokinetics and the safe use of Sarconeos in that specific population. Sarconeos will be administered to approximately 30 healthy elderly volunteers for 14 days, at 3 daily doses (100 mg, 350 mg, and 700 mg).
- A pilot characterization study in a pre-selected target population of patients suffering from Sarcopenia (the SARA-OBS study) will be conducted in Europe and the United States, to specify the clinical criteria for this new pathology, which will be used for recruitment in the main SARA study.

These two studies, which will be conducted in the second half of 2016, will enrich the Sarconeos clinical-regulatory file and facilitate filing of applications for Phase 2b testing in Belgium, France (IMPD Ph2), and the United States (IND Ph2) in the first half of 2017. The goal during the preparation time for this study, which is longer than originally proposed, is to better characterize the target elderly patient populations, reduce the risk of failure, and optimize the potential of Sarconeos in both Europe and the United States.

In line with this strategy, in the case of Macuneos for treatment of dry AMD, BIOPHYTIS will initiate a preparatory phase for the international study that will include:

- Conducting a pharmacokinetics and safety study among healthy older volunteers in Europe,
- A pilot characterization study in a pre-selected target population of patients suffering from dry AMD in the main recruiting centers in Europe and the United States.

Stanislas Veillet, Chief Executive Officer of BIOPHYTIS, said: *"Our strategic decision to increase our presence in the United States, and to involve that region more in the clinical development of our most advanced candidates, Sarconeos and Macuneos, is a strategic move which significantly impacts our plans. By nearly doubling the size of our SARA and MACA studies, we will increase their statistical power and the value of Sarconeos and Macuneos development programs. By conducting additional preliminary clinical studies, we will more accurately determine the conditions of administration of our products, and better target patients to be recruited in Europe and the United States for the phase 2 clinical studies. As a result, we will lengthen the preparation phase of the SARA and MACA studies and delay the start of the investigation by 12 to 18 months. BIOPHYTIS is the most advanced company in the world with regards to these pathologies with no marketed therapies. Our business strategy is to establish clinical proof of concept, prior to signing an agreement with a major pharmaceutical laboratory. Moreover, we are pleased to welcome Susanna del Signore who, as Medical Director, will be responsible for BIOPHYTIS' clinical development."*

Reinforcement of the management team with the appointment of Susanna Del Signore, MD, as Medical Director. Susanna Del Signore, a graduate of the University of Rome "La Sapienza," and an expert in Internal Medicine and Clinical Nutrition, began her career at the Servier International Research Institute, where she was in charge of project development, in particular in the area of the central nervous system. She next led the Neurodegenerative and Ophthalmic Diseases Department of the European Medicines Agency between 2005 and 2009. She then joined the Sanofi Group where she headed global regulatory policy until 2015. In recent years she has led several research consortia, in

particular in the area of sarcopenia (the SPRINT program with Sanofi, Novartis, GSK, Servier, and Eli Lilly). At BIOPHYTIS, she will be in charge of the medical department and will work together with executive management and opinion leaders.

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The 2015 "Document de Référence" can be downloaded on BIOPHYTIS' website :
http://www.biophytis.com/en/action/

All documents mentioned can be consulted at the Company's website (www.biophytis.com), in the "Investors" area, under the heading "Regulated Information." The Reference Document is also available at the AMF website (www.amf-france.org). Hardcopy versions of these documents with the audited financial statements may be obtained free of charge upon request.

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 discovered and 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: Sarcob (BIO101) to treat sarcopenic obesity and Maculia (BIO201) to treat dry age-related macular degeneration (AMD).
The company was founded in partnership with researchers at the UPMC (Pierre et 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).

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) 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 supersede.

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