Press release

BIOPHYTIS updates on clinical development of Macuneos and presents its effects on visual function in a preclinical model of AMD at 2018 ARVO Congress

Paris (France), April 27th, 2018, 6pm – BIOPHYTIS (Euronext Growth Paris : ALBPS), a biotechnology company specializing in the development of drug candidates for the treatment of degenerative age-related diseases, provides an update on the clinical development of Macuneos in the intermediate dry form of age-related macular degeneration (AMD) and announces that a poster has been selected for presentation at the Annual Meeting of the Association for Research in Vision and Ophthalmology (ARVO) in Honolulu, Hawaii, from April 29 to May 3, 2018. The results that will be presented demonstrate the great potential of Macuneos in age-related macular degeneration (AMD) and confirms the relevance of the MACA-PK clinical study, which is expected to start in the second half of 2018.

Stanislas Veillet, CEO of BIOPHYTIS, states*: "We are pleased to participate once again to the ARVO Annual Conference and present the results confirming the potential of Macuneos drug candidate in the treatment of the intermediate dry form of AMD. We have demonstrated that after prolonged oral administration, Macuneos was shown to significantly slow the loss of visual function in a preclinical model of dry AMD. These promising results encourage us to launch the MACA-PK clinical study from this summer. MACA-PK's design includes a first phase with single administration (SAD), the results of which should be published by the end of 2018, followed by a second phase with multiple administration (MAD) for 3 months on patients with intermediate AMD which should end in the second half of 2019. We will then have a better understanding of the safety profile, pharmacokinetics and pharmacodynamics of our drug candidate Macuneos, which is the only drug candidate in clinical development to treat dry AMD."*

MACA-PK is a randomized, double-blind, placebo-controlled, phase 1/2a study which aims to evaluate the safety, pharmacokinetic and pharmacodynamic profile in healthy volunteers in 2018 and to obtain first clinical data in patients with AMD in the first half of 2019. To carry out this study, Biophytis contracted the CRO SGS Life Science Services, supplemented by the CRO Appletree Medical Group. The study will be conducted in 10 clinical centers in France, the United Kingdom, Belgium and Hungary. The design of MACA-PK will proceed in two steps:

- In the first SAD phase (Single Ascending Dose), 40 healthy volunteers aged over 55 years, in 5 cohorts of 8 patients each, will receive a series of increasing single doses of Macuneos. In each cohort, 6 patients will receive one dose of Macuneos and 2 patients will receive placebo. The SAD phase will be conducted in the second half of 2018 in a specialised center located in Antwerp, Belgium. The ophthalmological parameters will be analysed in a second specialised center in the same city.
- The second MAD phase (Multiple Ascending Doses), which will be conducted in 2019, will evaluate patients with dry AMD. Three doses of Macuneos selected from the SAD's data, and having the most advantageous safety and pharmacokinetic profiles, will be tested successively for 84 days in AMD patients. It includes the evaluation of several pharmacodynamic parameters including microperimetry, ERG (Electro-RetinoGram), dark adaptation capacity, contrast sensitivity, and visual acuity in low light conditions. Patients in the MAD phase will be recruited in 5 French centers, including CIC l'Hôpital des Quinze-Vingt in Paris, 3 centers in the United Kingdom, 1 center in Hungary and 1 center in Belgium.

The MACA-OBS multicentric observational clinical study is expected to start in the second half of 2018, with the aim to characterize the evolution during a 6-month renewable period of retinopathy in the target population of Macuneos and to pre-recruit 100 patients with intermediate dry AMD in 10 ophthalmic clinical centers in Europe and the United States. These patients are intended to be included, if they consent, in the interventional study MACA-INT.

The objective of the interventional MACA-INT Phase 2b clinical trial, whose authorization applications are expected to be filed in France and the United States in the second half of 2019, is to assess the effective therapeutic dose of Macuneos on ederly patients with intermediate dry AMD that have a high probability of progressing to a severe form (exudative form or geographic atrophy). Once the authorizations have been obtained, recruitment should start at the end of the first half of 2020. The results of the MACA-INT clinical study are expected at the end of 2022.

Poster – 29th of April 2018

Title: **Chronic oral treatment with BIO201 preserves retinal function in a dry AMD experimental model**

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Summary: Dry AMD is a major cause of blindness in the elderly. Currently, only nutritional treatments display limited efficacy. We have previously established the photoprotective activity of BIO201, a pan PPAR ligand, on retinal pigment epithelial cells in vitro and in a mouse model of dry AMD in vivo. Here, BIO201 has been tested as a preventive and curative oral treatment in a mouse model of dry AMD. It demonstrated efficiency in maintaining retinal structure and electrical activity over 6-month administration. The drug candidate, developed by Biophytis, is currently entering clinical development in dry AMD patients.

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About MACUNEOS:

Macuneos is the first representative of a new class of drug candidates, the PPARs nuclear receptor agonist, protecting the retina from photo toxic effects of A2E, reducing its accumulation and slowing down in animal models retinal degeneration and loss of vision. Macuneos is in clinical development in intermediate AMD, a dry form, a retinopathy that affects the central part of the retina, called macula, causing the irreversible loss of central vision. Dry AMD is the leading cause of blindness on people over 50. It affects more than 30 million patients worldwide, without any treatment.

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

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