

BIOPHYTIS selects Appletree CI Group to conduct MACA-OBS, and releases the MACA clinical program schedule of Macuneos in dry AMD

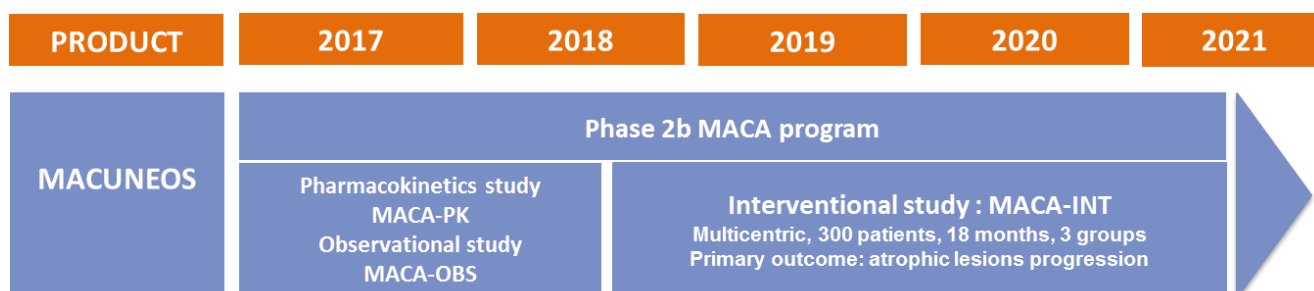
Paris (France), 19 July 2017, 18:00 - BIOPHYTIS (Euronext Growth Paris: ALBPS), a biotechnology company specializing in the development of drug candidates to treat age-related diseases, has announced the contracting of Appletree CI Group to conduct the MACA-OBS clinical study of its drug candidate Macuneos in the treatment of age-related macular degeneration (AMD). The objective of the MACA-OBS observational study is to characterize the target population and to preselect patients with dry AMD. Biophytis is waiting to be granted the regulatory authorizations in the second half of 2017 in order to open centers in Europe and the USA. Alongside MACA-PK, MACA-OBS is intended to prepare for the phase 2b MACA-INT interventional study which should be launched during the second half of 2018.

The multicentric observational MACA-OBS study aims at characterizing the target population and preselecting patients with dry AMD. For a period of 6 months, this study will involve one hundred patients with mild AMD distributed between 9 centers in Europe and the USA, including the Massachusetts Eye and Ear Infirmary (Harvard Medical School) in Boston. The regulatory authorizations for opening the centers are expected in the second half of 2017, thus allowing the start of MACA-OBS and following that, the recruitment of patients.

Biophytis has selected Appletree CI Group to conduct this international multicentric clinical study. Appletree CI Group is a Swiss Contracted Research Organization (CRO) which focusses on the development of ophthalmological and dermatological drug candidates. Appletree CI Group will provide its clinical research services and will also support Biophytis with regards to filings at the agencies in Europe and more widely at the international level.

Stanislas Veillet, CEO of BIOPHYTIS, said: *“The contracting of Appletree CI Group to conduct the clinical study MACA-OBS is an important indicator of our desire to develop the drug candidate Macuneos. The MACA-OBS study will begin after receiving the approval of the regulatory authorities in the second half of 2017. Along with MACA-PK, MACA-OBS serves to optimize the design of the phase 2b MACA-INT interventional study, which should be launched in the second half of 2018 and finish in 2021. The objective is to co-develop Macuneos after MACA-PK or MACA-INT with one or several partners capable of marketing this drug.”*

MACA clinical program schedule:



The MACA-OBS and MACA-PK studies are complimentary studies preparing for the MACA-INT interventional study. They will allow the preselection of 15 clinical ophthalmological centers in Europe and the USA and the pre-recruitment of patients with mild dry AMD who could be included, if they give their consent, into the MACA-INT interventional study. This international study will begin in the second half of 2018 and should conclude in 2021. It will involve more than 300 subjects aged over 50 with mild dry AMD, distributed between twenty clinical centers. The objective of MACA-INT is to determine the effective treatment dose of Macuneos, limiting the increase in size of the geographic atrophy in patients with mild dry AMD.

The key steps of the program are as follows:

- H2 17: MACA-PK SAD: Pharmacokinetics study in healthy volunteers (ending H2 17)
- H2 17: MACA-OBS: Initiation of observational phase (ending H1 18)
- H1 18: MACA-PK MAD: Pharmacokinetic study on patients (ending H1 18)
- H2 18: MACA-INT: Initiation of interventional Phase 2b
- H2 21: MACA-INT: Results report of Phase 2b

The business model of BIOPHYTIS is to ensure the conduct of the project until clinical activity is proven, then to license the technologies in order to continue the development in partnership with a pharmaceutical laboratory able to market the products. This laboratory will be responsible for obtaining market authorizations, Biophytis is therefore not releasing a forecasted date for receiving the market authorization.

About MACA-PK:

The MACA-PK study is a phase I/IIa clinical study, whose protocol has been optimized to study the safety, pharmacokinetics and pharmacodynamics of Macuneos in healthy volunteers in a Belgian clinical center in 2017 as originally planned, and in patients suffering from dry AMD recruited in 5 ophthalmological centers in France and in Belgium, including the CIC of l'Hôpital des Quinze-Vingt in Paris, in 2018. Biophytis has called on the CRO SGS Life Science Services to conduct this international multicentric clinical study.

About MACUNEOS:

Macuneos is the first representative of a new class of drug candidates, agonists of nuclear receptor PPAR. Macuneos protects retinal pigment epithelium: Biophytis has shown in animal models a protection of retinal cells against phototoxic effects of A2E in the presence of blue light (oxidative stress), a reduction in accumulation of A2E, and eventually a slowdown of the degenerative process of the retina. Macuneos is a drug candidate against the dry form of AMD: AMD affects the central part of the retina, called the macula, causing severe visual impairment and irreversible loss of central vision beyond 60 years old. Macuneos is in tablet form (once per day), containing 100 mg or 350 mg of active Pharmaceutical Ingredient (API).

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).

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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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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).

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