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NEW THERAPEUTICS FOR AGING DISEASES

Press release

BIOPHYTIS selects SGS Life Science Services to conduct MACA-PK, clinical study of Macuneos in dry AMD

Paris (France), 15th June 2017, 6.00pm - BIOPHYTIS (Alternext Paris: ALBPS), a biotechnology company specializing in the development of drug candidates to treat age-related diseases, has announced the contracting of SGS Life Science Services to conduct the MACA-PK clinical study of its drug candidate Macuneos in the treatment of age-related macular degeneration (AMD). The objective of MACA-PK is to study the safety, pharmacokinetics and pharmacodynamics of Macuneos in healthy volunteers in 2017 as originally planned, then in patients suffering from dry AMD in 2018, according to an optimized protocol.

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 Belgium, in 2018. Biophytis has called on the CRO SGS Life Science Services to conduct this multicentric international clinical study.

SGS is a leading international contracted research organization (CRO), with more than 35 years of experience in clinical research. SGS already successfully supported Biophytis in 2016 with the SARA-PK study of Sarconeos on Sarcopenia and currently supports Biophytis in its approaches to regulatory agencies, particularly in the US.

Stanislas Veillet, CEO of BIOPHYTIS, said: "*The protocol of the MACA-PK study has been optimized to evaluate the effect of Macuneos on the visual function of patients suffering from AMD, due to start in 2018. These elements will complete the safety data from the healthy volunteers that will have been gathered in 2017, as originally planned. These elements are key to launching the phase 2b MACA-INT study in the right conditions, which will start afterwards in the second half of 2018, but which we will have been preparing with the MACA-OBS observational study." He added: "Our objective is to pursue the development of Macuneos until the demonstration of its clinical activity and the safety of its use on patients suffering from AMD, in order to then co-develop Macuneos after MACA-PK or MACA-INT, in 2018 at the earliest, with one or several partners capable of commercializing this drug.*"

Macuneos (BIO201) is an oral treatment against dry AMD (80% of AMD cases), a market valued close to 30 billion dollars per year. The mode of action of Macuneos is based on the activation of PPAR receptors in order to limit the accumulation of A2E (a by-product of the degradation of the visual pigment involved in the oxidative process) and consequently slow down the retinal degeneration. The results of the previous clinical study on healthy individuals show that Macuneos already lends itself to oral administration, being fully absorbed at the intestinal level, reaching the retina, and in accordance with a daily dosage for a man comprising of between tens and hundreds of milligrams per day.

The MAKA-PK study comprises 3 phases:

- SAD (Single Ascending Dose) Phase: healthy volunteers over the age of 55 receive a series of single ascending doses of Macuneos. The SAD investigation phase is planned for the second half of 2017 and will be carried out in Anvers, Belgium.
- MAD (Multiple Ascending Dose) Phase: the three doses with the best profiles in terms of safety and pharmacokinetics will be successively tested in repeated doses for 28 days on patients suffering from dry AMD. The MAD clinical investigation phase will be carried out during the first half of 2018 with 36 patients. Notably, it includes the evaluation of several pharmacodynamics parameters including ERG (electoretinogram), adaptation to low light levels, sensitivity to contrast and visual acuity.
- Follow-up: an extension of 2 months will be proposed to the groups of patients that were tested in MAD on the condition that the regulatory authorities approve it.

The advantage of the new clinical protocol of MACA-PK is that it offers the opportunity to evaluate the effects of Macuneos on several pharmacodynamics parameters, in particular visual parameters, in patients suffering from dry AMD from 2018, before the launch of the Phase 2b MACA-INT interventional clinical study. The start of this study is expected in the second half of 2018 with the objective of choosing the effective treatment dose of Macuneos that can limit the increase in size of geographic atrophies in patients suffering from mild dry AMD. 300 patients will be recruited in twenty centers in Europe and the US. The preparation for this study includes the 2017 start of the MACA-OBS observational study, which in the first half of 2018 will allow the pre-recruitment of one hundred patients suffering from mild dry AMD, who could be included in MACA-INT if they give their consent, in at least 7 ophthalmological clinical centers in Europe and the US.

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).

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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 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 Alternext market of Euronext Paris (ALBPS; ISIN: FR0012816825).

For more information: http://www.biophytis.com

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