biophytis
NEW THERAPEUTICS FOR AGING DISEASES

Press Release

BIOPHYTIS: 2017 Annual Report filed

Update on recent progress and ongoing projects developments

Paris (France), July 26, 2018, 6pm - BIOPHYTIS (Euronext Growth Paris: ALBPS), a biotechnology company specializing in the development of drug candidates to treat age-related diseases, today announces the publication of the 2017 Annual Report (Document de référence). This document has been filed with the Autorité des Marchés Financiers (AMF) under number R18-058.

The document reviews the company's main achievements and projects under development, including:

Development of Sarconeos in sarcopenia: Phase 2B clinical study, SARA-INT

Following authorizations from the Food and Drug Agency (FDA) and the Belgian regulatory agency (FAMHP), the administration period of the interventional phase 2b study of SARA-INT started at the end of May with the enrollment of the first patient. Recruitment should be completed by the end of the year, which could deliver preliminary results by Q3 2019 and final results by the end of 2019.
In total, the placebo-controlled, double-blind Phase 2b SARA-INT trial will include approximately 334 patients in 22 clinical centers in Europe (Belgium, France and Italy) and in the United States. Nearly half of the patients will be recruited from the observational SARA-OBS study currently conducted in 11 clinical centers.

Development of Macuneos in AMD: Phase 1/2a clinical study, MACA-PK

The randomized, double-blind, placebo-controlled Phase 1/2a MACA-PK study aims to study the safety, pharmacokinetics and pharmacodynamics of Macuneos on patients with dry AMD. The clinical study protocol consists of a first phase on healthy volunteers in a clinical center in Belgium (SAD phase), followed by a second phase in patients with dry AMD recruited from several ophthalmic centers in Europe (MAD phase). The start of the study is planned this year with the aim to reach completion in 2019.

Development of Sarconeos in Duchenne Muscular Dystrophy: MYODA clinical program

Sarconeos has already received the orphan drug status granted by the FDA and the EMA (European Medicines Agency) in the Duchenne Muscular Dystrophy. This status will allow Biophytis to benefit from numerous incentives for the development of its drug candidate, including: assistance in the development of protocols, access to financing of the development of the drug candidate, access to a centralized marketing authorization procedure in Europe, and a marketing exclusivity of 10 years in the European Community and 7 years in the USA.
The next step is the submission of the Pediatric Investigation Plan to the EMA for opinion, and the finalization of the clinical development plan. Consisting of two studies, this program includes a phase 1/2a MYODA-PK pharmacokinetic study that could begin in 2018, and a phase 2/3 MYODA-INT efficacy study, which could start in 2019.

Strengthening of the team in the USA (Cambridge, MA)

In 2018 the team will be further strengthened to manage efficiently the clinical and regulatory development of Sarconeos and Macuneos, particularly in the United States. The recent recruitment of Dr Samuel Agus, the new Chief Medical Officer based in Cambridge (Massachusetts), is part of this strategy.

The Reference Document can be consulted on the Biophytis website: http://www.biophytis.com/ as well as on the AMF website: www.amf-france.org

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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 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 60. It affects more than 30 million patients worldwide, without any treatment. Macuneos is presented in tablet form (1 time per day), containing 100 mg or 350 mg of Active Pharmaceutical Ingredient.

About Duchenne Muscular Dystrophy:

Duchenne muscular dystrophy (DMD), is an X-linked inherited muscular disease, which concerns 1 in 3,500 male births, and characterized by progressive muscle weakness and cardiomyopathy, leading to premature death. Muscles undergo repeated cycles of necrosis/regeneration and are replaced by connective and adipose tissues. Glucocorticoids and supportive therapy are the current standard of care leaving many patients with an unmet medical need.

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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