

Biophytis receives favourable opinion from EMA for the Orphan Drug designation of Sarconeos in Duchenne Muscular Dystrophy (DMD)

Paris (France), May 28, 2018, 6pm - BIOPHYTIS (Euronext Growth Paris: ALBPS), a biotechnology company specialized in the development of drug candidates to treat age-related degenerative diseases, announces that the EMA (European Medicines Agency) has given a favorable opinion for Sarconeos to be designated as an Orphan Drug, its drug candidate in Muscular Dystrophy or Duchenne Muscular Dystrophy (DMD).

Stanislas Veillet, CEO of BIOPHYTIS, said: *"The positive opinion given by the EMA (which follows the favourable opinion of the FDA) is a significant regulatory step for the progress of this project, in order to provide a therapeutic response to patients with Duchenne muscular dystrophy. The next step is the submission of the Pediatric Investigation Plan, for scientific advice, to the EMA, and the finalization of the clinical development program. Consisting of two studies, this program includes a phase 1/2a MYODA-PK pharmacokinetic study which could begin in 2018 and a phase 2/3 MYODA-INT efficacy study which could start in 2019."*

Duchenne muscular dystrophy (DMD) is an orphan pediatric disease linked to a genetic abnormality. The young patients affected by this dystrophy see their muscles become damaged at each contraction, going as far as their total destruction. The respiratory, cardiac and digestive muscles in particular are affected in a progressive and irreversible way, thus affecting very significantly the life expectancy of the patients.

In the reference animal model, Sarconeos significantly improved exercise tolerance and muscle strength, and reduced fibrosis. While there are currently few effective treatment options, Sarconeos has the potential to significantly slow down the progression of the disease. It could be used as a standalone treatment, or in combination with gene therapy when it will be available for children with DMD.

The Committee for Orphan Medicinal Products (COMP) has given a favourable opinion that Sarconeos be designated an orphan drug in the treatment of Duchenne muscular dystrophy. This opinion is sent to the European Commission for approval, validating the orphan drug status of Sarconeos. This status will allow Biophytis to benefit from numerous incentives for the development of its drug candidate, including: assistance in the development of protocols, allocation of credits for the development of the drug candidate, access to a centralized marketing authorization procedure in Europe, and a 10-year marketing exclusivity in the European Community.

About MYODA:

MYODA is the name of drug candidate Sarconeos' new clinical development program in Muscular Dystrophy or Duchenne myopathy (DMD). Sarconeos is a drug candidate that activates the MAS receptor, stimulates muscle anabolism and reduces the appearance of muscle fibrosis, with the potential to suspend the disease's progression, particularly to delay the loss of mobility. The clinical development program will include a phase I/II pharmacokinetic study (MYODA-PK), which is expected to begin in 2018, and a phase II/III study (MYODA-INT), which is expected to start in 2019.

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 SARONEOS:

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 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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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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