Press release

Biophytis files for Orphan Drug Designation for Sarconeos in Duchenne Muscular Dystrophy (DMD)

Presentation of MYODA: a new clinical program in the treatment of Duchenne Muscular Dystrophy

Paris (France), March 20, 2018, 6.45pm - BIOPHYTIS (Euronext Growth Paris: ALBPS), a biotechnology company specializing in the development of drug candidates to treat age-related degenerative diseases, announces that it has filed for orphan drug designation with the European Medicines Agency (EMA) and presents MYODA, the new clinical program of Sarconeos in Duchenne Muscular Dystrophy (DMD).

Stanislas Veillet, CEO of BIOPHYTIS, comments: *"The filing for orphan drug designation with the EMA, and soon with the FDA, marks an important step in the development of Sarconeos in Duchenne Myopathy. The proofs of concept in animals, presented in 2017 at the World Muscle Society Congress, as well as the discussions with clinicians and patients' associations, prompted us to investigate the potential of Sarconeos in the treatment of this particularly severe orphan paediatric indication. We were able to specify the main elements of Sarconeos' clinical development plan in this muscular dystrophy, which will consist of two studies: a pharmacokinetic phase I/II MYODA-PK study, which is expected to begin in 2018 and an efficacy phase II/III MYODA-INT study, which could start in 2019. While there are very few effective treatment options, Sarconeos is a new class of drug candidate with the potential to significantly slow down the evolution of the disease and could be used as a standalone treatment or in combination with gene therapy when it will be made available for children with Duchenne Myopathy."*

- **The Orphan Drug Designation for Sarconeos in Duchenne Myopathy**

Biophytis has filed an application for an orphan drug designation for Sarconeos in Duchenne myopathy with the EMA and will file the same application with the FDA in the coming days. The agencies' answer is expected in the coming months and could give Sarconeos the benefits associated with the orphan drug status, in particular an accelerated registration procedure, and an 8 or 10 years protection after marketing authorization.
This application follows the proof-of-concept studies presented at the World Muscle Society congress in 2017, which demonstrated in the reference animal model of Duchenne Muscular Dystrophy, that Sarconeos had significantly improved exercise tolerance and muscle strength, and reduced muscle fibrosis. It is the first regulatory step to obtain authorizations to develop Sarconeos in Duchenne Muscular Dystrophy, in parallel with its development in Sarcopenia. It marks the implementation of a dual development strategy of Biophytis' drug candidates, not only in chronic geriatric diseases, but also in genetic degenerative diseases.

- **Sarconeos' clinical development plan in Duchenne myopathy**

Sarconeos' clinical development plan in Duchenne myopathy consists of two main clinical studies: a pharmacokinetic phase I/II MYODA-PK study to be initiated in 2018, and a phase II/III efficacy study, MYODA-INT, that could start in 2019. While there are very few effective treatment options, Sarconeos

is a new class of drug candidate that has the potential to significantly delay 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 Duchenne myopathy.

MYODA-PK

The MYODA-PK phase I/II study aims at validating Sarconeos' safety as well as its pharmacokinetics and pharmacodynamic profile in paediatric patients with Duchenne myopathy. For a duration of 4 weeks, the double-blind placebo-controlled study will be conducted in approximately 24 boys with Duchenne myopathy aged 2 to 18 years. It will be carried out in 2 phases: single-ascending dose (SAD) and multiple-ascending dose (MAD). Collected data will be used to assess dosage for the phase II/III clinical trial. MYODA-PK will take place in several paediatric investigation centers in Europe.

MYODA-INT

Multicentric international phase II/III MYODA-INT study will evaluate the safety and efficacy of a Sarconeos dose in about 60 ambulant boys with Duchenne myopathy. Of a minimal treatment duration of 6 months, the study will be randomized, double-blind, placebo-controlled. The primary endpoint will be the North Star Ambulatory Assessment (NSAA), used to measure functional motor abilities in ambulant children with DMD. Conducted in Europe and the United States, the results of this study should allow to file for a conditional marketing authorization.

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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 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 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.
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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BIOPHYTIS is eligible for the SMEs scheme

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