

Press release

# BIOPHYTIS chooses Patheon to produce the clinical batches of Macuneos, its AMD drug candidate that will enter Phase 2B

Romainville (France), October 24th, 2016, 7:30 - BIOPHYTIS (Alternext Paris: ALBPS), a biotechnology company specializing in the development of drug candidates to treat diseases of ageing, announced today that it has entered into an agreement with US firm Patheon for the industrial scale-up and manufacturing of clinical batches, the first stage of the phase 2B clinical trial for drug candidate Macuneos in AMD (age-related macular degeneration).

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 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.

As part of the agreement, Patheon will be in charge of the industrial scale-up and manufacture of Macuneos clinical batches. These lots will be used by BIOPHYTIS for the Phase 2B study MACA, to be launched in Europe and the United States once all approvals of regulatory authorities have been obtained.

**Stanislas Veillet CEO BIOPHYTIS**, said: "We are very pleased to outsource the production of Macuneos to such an internationally recognized actor. This is the first stage of the MACA clinical program dedicated to treat dry AMD, a pathology with no therapeutic solution on the market so far. Our whole team is dedicated to the success of the MACA clinical project, a strategic axis of development for BIOPHYTIS."

#### **About MACA**

The MACA phase 2B trial will involve 300 patients over 50 years of age with intermediate dry form of AMD, and should involve twenty centers in Europe and ten in the United States.

Patients enrolled in the study will be divided into three cohorts: Macuneos 100 mg, Macuneos 350 mg and placebo. The investigation period will be 18 months, with an intermediate checkpoint after 9 months.

The study will begin with a preparatory phase including:

- A pharmacokinetics and safety study will be conducted in Europe among healthy elder volunteers (the MACA-PK study),
- A pilot characterization study of the target population and a pre-selection of patients suffering from dry AMD in major recruitment centers in Europe and the US (the MACA-OBS study)

\*\*\*

#### **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 need. Specifically, the company is advancing two lead products into mid-stage clinical testing next 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





#### **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 Alternext 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 5 both French and English. In the event of any differences between the two texts, the French language version shall supersede.

## BIOPHYTIS Stanislas VEILLET

CEO

contact@biophytis.com Tel: +33 (0) 1 41 83 66 00 Milestones Press and investor relations Bruno ARABIAN

barabian@milestones.fr Tel: +33 (0) 1 83 62 34 84 Mob: +33 (0) 6 87 88 47 26

Citigate Dewe Rogerson
International press
Laurence BAULT/Antoine DENRY

Tel: +33 (0)1 53 32 84 78 Mob: +33(0)6 64 12 53 61

Laurence.bault@citigate.fr/antoine.denry@citigate.fr

### LifeSci Advisors Chris MAGGOS

Managing Director, Europe chris@lifesciadvisors.com Tel: +41 79 367 6254