

## BIOPHYTIS ready to launch SARA-OBS trial Design of observational study on sarcopenia SARA-OBS is finalized and regulatory filings have been submitted in France

Romainville, September 13, 2016, 7:30 am - BIOPHYTIS (Alternext Paris: ALBPS) a biotechnology company specialized in the development of drug candidates to treat ageing diseases, announces it has finalized the design, selected the main partners (clinical centres and CRO) and filed in France, for regulatory authorization for the SARA-OBS study in sarcopenia patients.

SARA-OBS is a clinical observational study aimed at recruiting and characterizing a patients' population diagnosed with sarcopenia, that could be ultimately enrolled in the phase 2b study, SARA-INT :

- 300 sarcopenic patients recruited according to the criteria defined by the Foundation for the National Institutes of Health<sup>1</sup>,
- 8 clinical centres in Europe and in the United States, will be involved, including Toulouse, Liege, Rome, Gainesville and Boston,
- Patients' mobility and muscular quality will be assessed for a period of 6 months, based on the following criteria: 6-minute walk test, muscle strength, muscular mass, plasma biomarkers of activity.

The results of the study will complete the clinical and regulatory file for Sarconeos, required for authorization to initiate the Phase 2b SARA-INT clinical study, in Europe and the United States, and by specifying patients' inclusion criteria.

**Stanislas Veillet, CEO of BIOPHYTIS, declares:** *“Everything is now set and we look forward to regulatory feedback that will allow us to initiate the SARA-OBS study. Through the choice of clinical centres, patient's population and assessment criteria, this study anticipates the phase 2b SARA-INT study. We are following the development plan according to the timelines communicated last April. We should be receiving authorizations to start SARA-OBS in target countries in the coming months.”*

### Constitution of an international Steering committee

An international steering committee has been constituted to oversee the SARA-OBS study. It is composed of:

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<sup>1</sup> Studenski et al., 2014. The FNIH Sarcopenia Project: Rationale, Study Description, Conference Recommendations, and Final Estimates. *J Gerontol A Biol Sci* 2014 May; 69(5): 547-558

- Pr Roger Fielding, PhD, director of the Nutrition, Exercise Physiology and Sarcopenia Laboratory (NEPS) at Tufts University in Boston, lecturer at the Harvard Medical School and member of the scientific committee of Biophytis,
- Pr Yves Rolland, gerontologist, Professor at Toulouse's university hospital, and practitioner at the Gerontopôle,
- Pr Marco Pahore, Director of University Florida Institute on Aging, Professor and Founding Chair, Department of Aging and Geriatric Research,
- Pr Olivier Bruyère, geriatrician and epidemiologist at Liège University.

This steering committee aims at ensuring the fulfilment of the study under the defined conditions and to evaluate the relevance of the SARA-OBS study's results.

### ICON chosen as CRO (Contract Research Organization) to supervise the study

A contract was signed with ICON in order to finalize the design of the SARA-OBS study, the qualification of the 8 clinical centres selected, the granting of regulatory approvals in the four countries where the study will take place (France, Belgium, Italy and the United States), the monitoring of around 300 patients recruited in Europe and in the United States and to collect and analyze observational data.

ICON is a world leader on the clinical studies market. Founded in Ireland, the company is today established in 37 countries with a strong presence in Europe and in the United States. For Biophytis, ICON is a highly experienced partner in clinical development in endocrine and metabolic pathologies, with a particular interest in sarcopenia for several years.

### Filing of regulatory authorization in France

France is the first country where regulatory approval has been submitted for SARA-OBS. The agreement should be reached in the coming weeks. The authorization submissions in the other targeted countries will be submitted during the second half of 2016.

### About SARCONEOS:

Sarconeos is the first representative of a new class of drug candidates, based on the activation of the MAS receptor (major player of the renin-angiotensin system) stimulating anabolism in the muscle, inhibitor of myostatin and favoring muscle mass development in animal models of muscular dystrophies. Sarconeos is developed in the treatment of sarcopenia, an age-related degeneration of skeletal muscle and strength, leading to a loss of mobility in elderly people. This new pathology, for which no medical treatment currently exists, was first described in 1993 and just entered the WHO International Classification of Diseases (M62.84), affects more than 50 million people worldwide.

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### About BIOPHYTIS:

Biophytis SA ([www.biophytis.com](http://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 et 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](http://www.amf-france.org)) or on BIOPHYTIS’ website ([www.biophytis.com](http://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.

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