

Biophytis Reports H1 2019 Financial Results and Provides Business Update

- *Achieved target number of 22 clinical sites opened and recruiting patients in the U.S. and Belgium. Filed protocol amendment with the regulatory agencies in both countries to optimize the SARA-INT Phase 2b clinical trial*
- *SARA-INT patient recruitment expected to be completed in mid-2020 with topline results by end of 2020*
- *IND to be filed with FDA for MYODA program in DMD in Q4 2019*

Paris (France), Cambridge (Massachusetts, U.S.), October 31, 2019, 08:00 CET - Biophytis SA (Euronext Growth Paris: ALBPS), a clinical-stage biotechnology company with a primary focus on the development of its lead drug candidate, Sarconeos (BIO101), for the treatment of neuromuscular diseases, today provides a business update and publishes its interim financial report for the 1st half of 2019, which are available on the Company's website.

Stanislas Veillet, Chief Executive Officer, stated: *"Biophytis has made strong operational progress in 2019, delivering multiple milestones as we execute our strategy, which is focused on the development of Sarconeos (BIO101) in sarcopenia and Duchenne muscular dystrophy (DMD). We have completed the SARA-OBS observation study, which preliminary analysis has led us to file an amendment with the U.S. Food and Drug Administration (FDA) to optimize the SARA-INT Phase 2b clinical trial. This protocol amendment aims to reduce the number of participants that is needed in the trial and to potentially accelerate the timeline.*

Throughout 2019, we have been focused on driving patient recruitment in the SARA-INT trial, including opening new clinical centers so that we can complete enrollment in mid-2020 and report top line results by end of 2020. We believe generating SARA-INT results will be a major milestone as sarcopenia remains an important unmet medical need due to the disability, and mortality it causes, and the fact that there are currently no approved medications to prevent or slowdown disease progression. Additionally, we are excited about the progress we have made with our MYODA clinical program in DMD and plan to file an investigational new drug (IND) application with the FDA before the year end."

Income Statement Summary ^(*)

<u>(amounts in thousands of euros, except share data)</u>	For the Half Years Ended June 30,	
	2018	2019
Research and development, net	(4,136)	(4,828)
General and administrative expenses	(1,542)	(4,789)
Operating Loss	(5,678)	(9,617)
Net financial expense	(12)	(581)
Loss before taxes	(5,690)	(10,198)
Income taxes benefit	-	-
Net loss	(5,690)	(10,198)
Basic and diluted weighted average number of shares outstanding	13,410,659	13,366,218
Basic and diluted loss per share (€/share)	(0.42)	(0.76)

(*) the interim 2019 consolidated financial statements were subject to limited review by the Statutory Auditors.



Operational Update

- **SARA clinical program in sarcopenia.** During the 2nd quarter of 2019, we completed the SARA-OBS study of 218 participants with sarcopenia in the U.S. and Europe (France, Italy and Belgium). The SARA-OBS study was designed to better understand disease progression in the target population of the SARA-INT Phase 2b clinical trial and to inform on the design and sample size.

In October 2019, based on preliminary analysis of the SARA-OBS data, Biophytis filed an amendment to the SARA-INT clinical trial protocol with the U.S. FDA and Belgian AFMPS, which proposes a reduction in patient population and includes a plan for an unblinded interim analysis. The goal of the interim analysis is to reconfirm patient deterioration of mobility over 6 months and to assess the likelihood of trial success of the SARA-INT study based on the revised patient population size. (see press release from October 31st, 2019)

In October 2019, we also reached our target of 22 clinical centers open in the U.S. and Belgium, including leading hospitals and geriatric centers for the ongoing SARA-INT clinical trial.

Based on these achievements, we currently expect to complete patient recruitment in mid-2020 and report topline results by end of 2020 for the SARA-INT Phase 2b trial.

- **MYODA clinical program in Duchenne muscular dystrophy (DMD).** In 2019, we continued our preclinical and regulatory efforts for the MYODA clinical program, which intends to use a seamless trial design from Phase 1 to 3 and a composite score to assess the safety and efficacy of a pediatric formulation of Sarconeos (BIO101) for both ambulatory and non-ambulatory patients with DMD.

In October 2019, we presented three posters on Sarconeos (BIO101) in DMD at the 24th Annual Congress of the World Muscle Society (WMS) in Copenhagen, Denmark, which provided details on the proposed seamless trial design and composite score, as well as preclinical respiratory data in animal models of DMD.

We are on schedule to submit an IND application to the FDA and clinical trial applications to the applicable regulatory agencies in Europe before the end of 2019.

Governance Update

- **Board of Directors.** Effective as of October 29, 2019, Mr. Eric Rowinsky has resigned from the Board for personal reasons and to focus his activities in the field of oncology. Professor Jean Mariani, MD, PhD, current Chairman of Biophytis' Scientific Advisory Board (SAB) has been added to the Company's Board of Directors, effective as of October 29, 2019. He is a professor at Sorbonne University (formerly the Pierre and Marie Curie University) in Paris, one of the largest European universities specializing in science and medicine, where he teaches neuroscience and the biology of aging. Professor Mariani is the Director of the University Hospital Department FAST (Fight Ageing and Stress), a multi-unit network of excellence conducting research into age-related diseases, and also the Director of the Charles Foix Institute of Longevity. Professor Mariani will remain Chairman of our SAB.

Interim 2019 Financial Results

- **Cash and Cash Equivalents.** Cash and cash equivalents as of June 30, 2019 were €5.2 million, a decrease of €9.2 million as compared to €14.4 million as of December 31, 2018. During the 1st half of



2019, cash used in operating activities and investing activities were €10.4 million and €0.3 million, respectively, which were partially offset by cash provided by financing activities of €1.5 million.

- **Research and Development Expenses.** Net research and development expenses were €4.8 million for the 1st half of 2019, an increase of €0.7 million as compared to €4.1 million for the 1st half of 2018. This increase in net research and development expenses was primarily related to the advancement of our lead drug candidate, Sarconeos (BIO101), including conducting the SARA-INT Phase 2b clinical trial in sarcopenia, as well as preclinical and regulatory development of our MYODA program in DMD.
- **General and Administrative Expenses.** General and administrative expenses were €4.8 million for the 1st half of 2019, an increase of €3.3 million as compared to €1.5 million for the 1st half of 2018. This increase in general and administrative expenses was primarily related to the one-time costs associated with the postponed Nasdaq listing in the U.S.
- **Net Loss.** Net loss was €10.2 million for the 1st half of 2019, as compared to €5.7 million for the 1st half of 2018. Net loss per share (based on weighted-average number of shares outstanding over the period) was €0.76 for the 1st half of 2019 and €0.42 for the 1st half of 2018.

In order to cover the Company's future financing requirements for the next 12 months, Biophytis assumes access to the following instruments:

- The line of funding set up with Negma allowing up to €24 million of financing to be raised through the issuance of convertible bonds and warrants (ORNANEBSAs), of which the first tranche of €3 million has been drawn to date; and
- The expected reimbursement of the 2018 Research Tax Credit (CIR) for €3.1 million.

The share capital of Biophytis is comprised of 16,563,254 ordinary shares outstanding as of October 29, 2019.

About Biophytis

Biophytis is a clinical-stage biotechnology company focused on developing therapeutics that slow the degenerative processes associated with aging and improve functional outcomes for patients suffering from age-related diseases, with a primary focus on neuromuscular diseases.

Biophytis' lead drug candidate, Sarconeos (BIO101), is an orally administered small molecule, which is currently in a Phase 2b clinical trial for sarcopenia (SARA-INT) in the U.S. and Europe. A pediatric formulation of Sarconeos (BIO101) is being developed for the treatment of Duchenne muscular dystrophy (DMD). Biophytis expects Sarconeos (BIO101) to be ready to enter the clinic for DMD in 2020, subject to regulatory approval. Biophytis' preclinical drug candidate, Macuneos (BIO201), is an orally administered small molecule in development for the treatment of retinopathies, including dry age-related macular degeneration (AMD) and Stargardt disease.

Biophytis is headquartered in Paris, France, and has offices in Cambridge, Massachusetts. The Company's ordinary shares are listed on Euronext Growth Paris (Ticker: ALBPS - ISIN: FR0012816825). For more information please visit 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 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 securities of Biophytis in any country. Existing and prospective investors are cautioned not to place undue reliance on these forward-looking statements and estimates, which speak only as of the date hereof. Other than as required by applicable law, Biophytis undertakes no obligation to update or revise the information contained in this press release. 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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