

## Biophytis Reports 2019 Full Year Results and Provides Operational Update

- ✓ Successful completion of our SARA-OBS observational study in sarcopenia supporting the SARA-INT Phase 2b study
- ✓ Protocol amendment for SARA-INT study approved by FDA resulting in a reduction of the cohort size from 334 to 231 patients; topline results expected by end 2020
- ✓ Acceleration of recruitment in SARA-INT study with 227 patients now recruited in 22 clinical centers in the US and Europe
- ✓ IND granted by FDA to start the clinical development of Sarconeos (BIO101) in Duchenne Muscular Dystrophy (DMD)
- ✓ Consolidation of financial resources through successful completion of a private equity placement of €3.3 million and a contracted convertible bond financing of up to €24 million with Negma

Paris, France, Cambridge (Massachusetts, United States), March 17, 2019, 8:00 am 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 announces its audited financial results for the year ended December 31, 2019, and provides updates on key operational developments.

**Stanislas Veillet, President and CEO of Biophytis**, said: «*Biophytis has made significant progress in the last several months. The FDA approval of our protocol amendment for the SARA-INT study with Sarconeos (BIO101), along with the acceleration in patient inclusion means we expect to complete recruitment of this important trial in the coming weeks. The recent equity financing will allow us to start the clinical development of BIO101 in Duchenne Muscular Dystrophy (DMD) and to complete the SARA-INT study, for which topline results are expected by the end of 2020. I am looking forward to the next 12 months with confidence.* »

The Company's annual 2019 consolidated financial statements prepared in accordance with IFRS were approved by the Company's Board of Directors on March 13, 2020. Audit procedures were completed, the issuance of the audit report is pending, and will be included in the Company's upcoming 2019 annual financial report.

### Annual 2019 Financial Results

• **Cash and Cash Equivalents.** Cash and cash equivalents as of December 31, 2019 were €6.3 million, a decrease of €8.1 million compared to €14.4 million as of December 31, 2018. During 2019, cash used in

operating activities and investing activities was €15.3 million and €0.3 million respectively. This was partially offset by €7.5 million of cash provided by financing activities.

- **Research and Development Expenses.** Net research and development expenses were €9.0 million for 2019, a decrease of €0.5 million compared to €9.5 million for 2018. This slight decrease reflects the company's prioritization of its financial resources to advance the SARA-INT Phase 2b clinical trial in sarcopenia, and the MYODA IND filing for DMD with the US & French regulatory authorities. This focus allowed to significantly accelerate patient enrollment into the SARA-INT clinical trial, as well as gain FDA authorization in December 2019 to start the MYODA trial.

Net research and development expenses included research tax credits (French '*Crédit Impôt Recherche*', or CIR) and other subsidies totaling €2.8 million in 2019 compared to €3.1 million in 2018.

- **General and Administrative Expenses.** General and administrative expenses were €6.6 million for 2019, an increase of €2.3 million compared to €4.3 million for 2018. This increase in general and administrative expenses was primarily related to the fees and expenses linked to the proposed listing of the Company's shares on Nasdaq and the expansion of our operations in the US.

- **Net Loss.** Net loss was €17.8 million for 2019, as compared to €14.0 million for 2018. Net loss per share (based on weighted-average number of shares outstanding over the period except the treasury shares) was €1.05 in both 2019 and 2018.

The table below summarizes operating results.

(amounts in thousands of euros, except share data)	2019	2018
Net Research and development expenses	(9,089)	(9,513)
General and administrative expenses	(6,593)	(4,348)
<b>Operating Loss</b>	<b>(15,682)</b>	<b>(13,861)</b>
Net financial expenses	(2,134)	(198)
<b>Loss before taxes</b>	<b>(17,816)</b>	<b>(14,059)</b>
Income taxes benefit	28	72
<b>Net loss</b>	<b>(17,788)</b>	<b>(13,987)</b>
Non diluted weighted average number of shares outstanding, except treasury shares	16 882 661	13,374,426
<b>Basic and diluted loss per share (€/share)</b>	<b>(1,05)</b>	<b>(1,05)</b>

## Operational updates

### SARA clinical program in sarcopenia :

- In April 2019, the Company completed the observational SARA-OBS study with 218 sarcopenia patients in the US and Europe (France, Italy and Belgium). The SARA-OBS study was designed to better understand disease progression in the target population of the phase 2b SARA-INT clinical trial in sarcopenia, and to provide further data on the design of the clinical trial and the number of patients that were needed to be recruited in to the study.

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- In October 2019, following the preliminary analysis of the SARA-OBS study, including a 6 month assessment of the 400 meters walking test (400MWT), the Company was able to confirm that the target population for the SARA-INT study is optimal, and that indeed these are patients that are at high risk for mobility disability.

Based on this analysis, the Company filed a protocol amendment for the phase 2b SARA-INT clinical trial with the FDA and AFMPS. The amendment proposed a reduction in the number of patients that needed to be recruited into the study from 334 to 231. The amendment also included an interim analysis on patients' mobility after 6 months to estimate the probability of success of the SARA-INT study based on the lower number of patients to be included in the trial.

- In October 2019, the company reached its objective of opening 22 clinical sites in the SARA-INT clinical trial, including globally recognized hospitals and geriatric centres in the US and Belgium.
- In December 2019, the company presented the preliminary analysis of the SARA-OBS study at the 12th Annual Congress of The Society on Sarcopenia, Cachexia and Wasting Disorders (SCWD) in Berlin, Germany. The company also presented the preliminary results in March 2020 at the 10<sup>th</sup> International Conference on Frailty and Sarcopenia Research (ICFSR 2020) in Toulouse, France.
- In February 2020, the Company announced the protocol amendment approval filed in October 2019, as well as an increase in the rate of recruitment of patients into the SARA-INT study. At that time 80% of the revised patient recruitment target had been reached. Completion of patient recruitment is expected in Q2 2020, and an interim analysis by the study's data safety and monitoring board (DSMB) is also expected to take place in Q2 2020.

### **MYODA clinical program in DMD:**

#### **Regulatory agencies have been consulted about the design of the planned MYODA clinical program for BIO101 in Duchenne Muscular Dystrophy (DMD) :**

- In 2019, the Company continued its preclinical and regulatory efforts in support of the planned MYODA clinical program. This program intends to use a 'seamless' clinical trial design that will encompass all three phases of clinical development (Phase 1 to Phase 3), using several criteria, including respiratory function and muscular strength. This clinical trial will evaluate safety and efficacy of a pediatric formulation of BIO101 for ambulatory and non-ambulatory DMD patients.
- In June 2019, the Company announced a €400.000 financing from AFM Téléthon as part of a collaboration to develop BIO101 in DMD.
- In October 2019, the Company presented three posters on BIO101 in relation to its development for DMD at the 24th annual congress of the World Muscle Society (WMS) in Copenhagen, Denmark. Biophytis provided details about the clinical trial protocol, as well as the respiratory data obtained in DMD animal models.
- In November 2019, the Company filed an IND with the FDA, which was granted in December 2019.

**MACA clinical program in Age-related Macular Degeneration :**

Non-clinical regulatory formulation work has been undertaken to prepare for the MACA clinical program in AMD.

**Financing :**

Following the company withdrawal of its public offering on Nasdaq at the end of July 2019, the Company secured a line of funding that could reach €24 million, set up with Negma (in August 2019).

The instrument is in the form of 2,400 note warrants for Bonds Redeemable in Cash or New or Existing Shares (ORNANE), at a par value of €10,000 each, combined with Share Subscription Warrants (BSAs), together referred to as ORNANEBSA. The €24m financing can be exercised for 4 years, without obligation to do so, through 8 successive tranches of €3 million each.

In addition, on February 12 2020, the company successfully completed a private placement for a total amount of approximately €3,3 million. Securities were subscribed by European and American institutional investors, most of whom have supported the company since its IPO.

The placement price was set at €0.27 per share following an accelerated order book construction procedure. This price corresponds to a 29.5% discount to the weighted average Biophytis stock price over the last 10 trading sessions prior to the private placement.

**Corporate governance and appointments:**

In April 2019, the Board of Directors noted the resignation of Mr Jean-Gérard Galvez as a member of the Board.

In October 2019, the Board of Directors named Mr Jean Mariani as a new Director of the Board, (pending the confirmation of his appointment at the next shareholder meeting). Mr Mariani replaced Mr Eric Rowinsky following his resignation.

In January 2020, Biophytis announced the appointment of Evelyne Nguyen as Chief Financial Officer (CFO). The Board also appointed Pierre J. Dilda, PhD, as Chief Scientific Officer (CSO) replacing Professor René Lafont, who became Scientific Advisor; and Waly Dioh, PhD, as Chief Operating Officer (COO).

**2020 outlook :**

Predictable changes for 2020 in two main areas:

1/ Completion of the phase 2b clinical study of Sarconeos (BIO101) in sarcopenia to obtain clinical proof of concept, particularly in terms of efficacy, safety, and tolerance in patients with severe symptoms.

It is important to note that Sarconeos (BIO101) is the only drug candidate currently in an advanced stage of development in humans for sarcopenia, a pathology that can affect between 6 and 22% of people aged 65 and more.



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2/ Start of the clinical trial of Sarconeos (BIO101) in DMD following the IND approval from the FDA. The aim is to open at least two clinical centers in the US and recruit the first patient in 2020.

### Coronavirus Statement

In view of the current and rapidly changing COVID-19 situation, Biophytis is taking the necessary steps to protect its employees, partners and operations.

Biophytis' employees, both in France and the US, have been asked to work from home and hold meetings and events virtually wherever possible. There is no travel to restricted areas for work-related reasons.

To date, we have seen limited impact on our daily operations, including our interactions with clinical investigators, regulators, the scientific community and other stakeholders.

As a result, we remain on track in all key areas, particularly with regard to our Phase 2b SARA-INT trial, where we expect to complete patient recruitment in the coming weeks.

However the situation might evolve. While follow up of participants in the SARA-INT study is currently running smoothly, we are monitoring the situation closely and assessing various options to continue with participants' follow up in a timely manner in order to complete the study as planned.

### About BIOPHYTIS

Biophytis SA is a clinically staged biotechnology company specializing in the development of drug candidates to slow down degenerative processes and improve functional abilities in patients with age-related diseases, particularly neuromuscular diseases.

Sarconeos (BIO101), our leading drug candidate, is a small molecule, administered orally, currently in clinical phase 2b in sarcopenia (SARA-INT) in the United States and Europe. A pediatric formulation of BIO101 is being developed for the treatment of Duchenne myopathy (DMD) for which the company received IND status by the U.S. Food and Drug Administration (FDA) in December 2019.

The company is based in Paris, France, and Cambridge, Massachusetts. The company's common shares are listed on the Euronext Growth Paris market (Ticker: ALBPS -ISIN: FR0012816825). For more information [www.biophytis.com](http://www.biophytis.com).

### Disclaimer

This press release contains forward-looking statements. While the Company considers its projections to be based on reasonable assumptions, these forward-looking statements may be called into question by a number of hazards and uncertainties, so that actual results may differ materially from those anticipated in such forward-looking statements. For a description of the risks and uncertainties likely to affect the results, BIOPHYTIS' financial position, performance or achievements and thus cause a change



## Press release

from the forward-looking statements, please refer to the "Risk Factors" section of the Company's 2018 Annual Report available on BIOPHYTIS website ( [www.biophytis.com](http://www.biophytis.com)).

This press release, and the information contained in it, does not constitute an offer to sell or subscribe, nor the solicitation of a purchase or subscription order, of BIOPHYTIS shares in any country. The elements contained in this communication may contain forward-looking information involving risks and uncertainties. The Company's actual achievements may differ materially from those anticipated in this information due to different risk and uncertainty factors. This press release was written in French and English; If there is a difference between the texts, the French version will prevail.

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