Press Release

BIOPHYTIS ANNOUNCES TOP LINE RESULTS OF SARA-INT PHASE 2 STUDY WITH SARCONEOS (BIO101) IN SARCOPENIA

- Sarconeos (BIO101) at the highest dose (350 mg bid) showed a clinically meaningful improvement in the 400-meter walk test (400MWT), the primary endpoint of the study
- Sarconeos (BIO101) showed a very good safety profile at the doses of 175 mg bid and of 350 mg bid with no Serious Adverse Events (AE) related to the product

Paris, France, and Cambridge, Massachusetts, USA – August 2, 2021, 8:00 a.m. CET – Biophytis SA (NasdaqCM: BPTS, Euronext Growth Paris: ALBPS), ("Biophytis" or the "company") is a clinical-stage biotechnology company focused on the development of therapeutics that slow the degenerative processes associated with aging and improve functional outcomes for patients suffering from age-related diseases, including severe respiratory failure in patients suffering from COVID-19, today announces the top line results of the SARA-INT phase 2 clinical study with Sarconeos (BIO101) in Sarcopenia:

The effect of two doses of Sarconeos (BIO101), 175 mg bid and 350 mg bid, have been compared to placebo on gait speed as measured by the 400-Meter Walk Test (400 MWT), the primary end-point of the study, in the Full Analysis Dataset (FAS) and in the Per-Protocol population (PP, subset of participants that complied to the clinical protocol).

Efficacy

Sarconeos (BIO101) at the highest dose of 350 mg bid showed a clinically meaningful improvement compared to placebo in gait speed, as measured in the 400MWT after 6 months of treatment, of 0.09 m/s in the FAS population and 0.10 m/s in the PP population (treatment effect significant, $p < 0.01$). The effect of Sarconeos (BIO101) at 350 mg bid is close to the Minimal Clinically Important Difference (MCID) in sarcopenia (0.1 m/s), associated with a reduction in mobility disability and mortality in elderly. Sarconeos (BIO101) at the lowest dose of 175 mg bid did not show a clinically meaningful difference compared to placebo in gait speed after 6 months of treatment neither in the FAS population (0.04 m/s), nor in the PP population.

No treatment effect was detected on the handgrip strength test and on PF10 sub-score of the SF-36 PRO on mobility disability, key secondary endpoints of the study. A full report of the results, including analysis of other secondary end-points and biomarkers and analysis in sub-populations, will be presented during a dedicated seminar at the International Congress on Frailty and Sarcopenia Research (ICFSR) to be held virtually from September 29 to October 02, 2021.

Roger A. Fielding, PhD, who heads of the Nutrition, Exercise Physiology & Sarcopenia team at Tufts University in Boston and Principal Investigator of SARA-INT trial declares: "The SARA-INT results are encouraging based on the 400MWT gait speed improvement at certain doses, a critical assessment for seniors at risk of mobility disability."

Jean Mariani, MD, PhD, Professor of Neurosciences and Biology of Aging at Sorbonne University, Chief Medical Officer of Biophytis said: "The results of Sarconeos (BIO101) on the 400MWT as the primary endpoint are promising since no other alternative treatment exists as of today. This paves the route towards an upcoming confirmatory phase 3 study in sarcopenia and further continue the development of Sarconeos (BIO101) in this indication".

Stanislas Veillet, CEO of Biophytis said: "Despites COVID-19 pandemic, the SARA team has been able to demonstrate the potential of Sarconeos (BIO101) in sarcopenia. This is a key milestone for the company after 15 years of research and development together with Sorbonne University. We are now committed to progress Sarconeos (BIO101) into phase 3 either alone or through partnerships with pharmaceutical companies."

Safety

Sarconeos (BIO101) showed a very good safety profile after up to 9 months of dosing, with no significant difference between treatments arms (175 mg bid or 350 mg bid) and placebo for Adverse Events, Serious Adverse Events, safety laboratory parameters and vital signs.
Adverse Events percentages - were 36%, 37% and 27% of the total Adverse Events for the placebo, 175 mg bid, 350 mg bid treatments respectively. Serious Adverse Events percentages - were 45%, 42% and 12% for placebo, 175 mg bid, 350 mg bid respectively. None of the Serious Adverse Events were related to the product according to investigators.

Impact of the COVID-19 pandemic

The COVID-19 pandemic and its related restrictions had a significant impact on the conduct of the study, mostly on the quality of the data and the power of the study, as participants were not allowed to perform their on-site visits from March 2020 until more favorable sanitary conditions were observed locally. 138 participants (59%) were still active in the study when COVID-19-related restrictions occurred. A total of 99 participants (43%) were not allowed to perform any physical assessment on site while on treatment, despites extension of the treatment period from 6 to 9 months. Treatment effects on the primary endpoint have been detected despite the negative impact of the COVID-19 pandemic.

The SARA-INT protocol

The aim of the SARA-INT study was to evaluate the safety and efficacy of Sarconeos (BIO101) for the treatment of age-related sarcopenia, leading to muscle atrophy and mobility disability. 233 participants enrolled in 22 clinical centers in the USA and in Belgium, were randomized in three treatment arms (175 mg bid, 350 mg bid versus placebo) and followed-up up to 6 months, adjusted to 9 months during COVID-19 pandemic. Participants have been included on the study mainly based on age (>65 years old), low Appendicular Lean Mass (ALM) adjusted by Body-Mass Index (BMI) combined with reduced mobility assessed by the Short Physical Performance Battery index (SPPB ≤ 8). Efficacy was evaluated based on the gait speed from the 400-Meter Walk Test (400MWT) as the primary endpoint, in the Full Analysis Set population (FAS, all randomized participants ie 233 participants) and in the Per-Protocol population (PP, subset of participants that complied to the clinical protocol ie 152 participants). Handgrip strength and Patient-Reported Outcome (PRO) of mobility capacity as measured with the SF-36 questionnaire are key secondary endpoints.
For more information, please refer to: https://clinicaltrials.gov/ct2/show/NCT03452488

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About BIOPHYTIS

Biophytis SA is a clinical-stage biotechnology company specialized in the development of therapeutics that are aimed at slowing the degenerative processes associated with aging and improving functional outcomes for patients suffering from age-related diseases, including severe respiratory failure in patients suffering from COVID-19.Sarconeos (BIO101), our leading drug candidate, is a small molecule, administered orally, being developed as a treatment for sarcopenia in a Phase 2 clinical trial in the United States and Europe (SARA-INT). It is also being studied in a clinical two-part Phase 2-3 study (COVA) for the treatment of severe respiratory manifestations of COVID-19 in Europe, Latin America, and the US. A pediatric formulation of Sarconeos (BIO101) is being developed for the treatment of Duchenne Muscular Dystrophy (DMD). The company is based in Paris, France, and Cambridge, Massachusetts. The company's ordinary shares are listed on Euronext Growth (Ticker: ALBPS -ISIN: FR0012816825) and the ADS (American Depositary Shares) are listed on Nasdaq (Ticker BPTS – ISIN : US09076G1040).For more information visit www.biophytis.com

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