

Notice regarding an initiation of Phase 2 clinical trial by BioAge aimed at treating older patients of COVID-19

OSAKA, Japan, March, 23 and 23, 2021 - Shionogi & Co., Ltd. (Head Office: Osaka, Japan; President and CEO: Isao Teshirogi, Ph.D. hereafter "Shionogi") today announced that BioAge Labs, Inc. (Head Office: Richmond, California, U.S.A.; CEO: Kristen Fortney, Ph.D., hereafter "BioAge") has initiated a [Phase 2 clinical trial](#) of asapiprant (prostaglandin D₂ DP1 receptor antagonist, S-555739, BioAge code: BGE-175) to suppress the exacerbation of older COVID-19 patients.

BGE-175 is a DP1 receptor antagonist discovered by Shionogi. Several non-clinical studies and clinical trials in over 2,400 subjects have shown that BGE-175 has high affinity and selectivity for the DP1 receptor¹ and is well tolerated and safe. In a study conducted by BioAge, administration of BGE-175 in aged mice infected with SARS-CoV-2 significantly decreased the mortality rate and viral load in the lungs.

Based on the favorable results of non-clinical studies, BioAge has initiated a Phase 2 clinical trial in older patients with COVID-19. Shionogi is supporting BioAge's rapid initiation of the clinical trial by supplying investigational drugs and cooperating with the IND application to the US FDA.

Shionogi is committed to “protect people worldwide from the threat of infectious diseases” as our key focus. We are not limiting ourselves to the research and development of therapeutics, but are also pursuing total care for infectious diseases, through awareness building, prevention, diagnosis, and addressing exacerbations, as well as the treating the infection itself. As a leading company to fight infectious diseases, in order to contribute to the recovery of social security and safety through the early termination of COVID-19, we are working on the development of new therapeutic drugs and vaccines and maximizing the value of existing compounds. In addition, we will strengthen our efforts, including collaboration with external partners, to provide healthcare solutions to a larger number of patients.

Future Outlook

The impact of this matter on the consolidated earnings forecast for the fiscal year ending March 31, 2021 will be limited at this time, but we will promptly announce any future impact on our financial results when recognized.

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About the Phase 2 clinical trial

The multicenter, placebo-controlled, randomized, parallel-group, double-blind study will recruit patients ≥ 60 years old hospitalized for COVID-19 who are not yet in respiratory failure. A total of 132 participants will receive daily doses of BGE-175 or placebo (66 in each group) for up to 14 days. The study medication will be administered orally or, in patients who cannot swallow, nasogastrically. The trial is being conducted in the US, Argentina, and Brazil. The primary endpoint is the proportion of patients who die or progress to respiratory failure 28 days after receiving the first dose of BGE-175. Full details of the trial are available at [ClinicalTrials.gov](https://clinicaltrials.gov).

About Shionogi & Co., Ltd.

Shionogi & Co., Ltd. is a major research-driven pharmaceutical company dedicated to bringing benefits to patients based on its corporate philosophy of “supplying the best possible medicine to protect the health and wellbeing of the patients we serve.” Shionogi’s research and development currently targets two therapeutic areas: infectious diseases, and pain/CNS disorders. For over 50 years, Shionogi has developed and commercialized innovative oral and parenteral anti-infectives. In addition, Shionogi is engaged in new research areas, such as obesity/geriatric metabolic diseases and oncology/immunology. Contributing to the health and QOL of patients around the world through development in these therapeutic areas is Shionogi’s primary goal. For more details, please visit www.shionogi.co.jp/en/.

About BioAge Labs, Inc.

BioAge is a clinical-stage biotechnology company that develops drugs to treat aging and aging-related diseases. BioAge has built a systems biology platform to map out the key molecular pathways that impact healthy human aging, based on proprietary human aging cohorts that have blood samples collected up to 45 years ago with participant -omics data that is tied to detailed medical follow-up records over their lifespan. To date, BioAge has raised \$127M from Andreessen Horowitz, Kaiser Foundation Hospitals, and others. BioAge’s mission is to develop a pipeline of therapeutic assets that increase healthspan and lifespan.

Forward Looking Statement

This announcement contains forward-looking statements. These statements are based on expectations in light of the information currently available, assumptions that are subject to risks and uncertainties which could cause actual results to differ materially from these

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statements. Risks and uncertainties include general domestic and international economic conditions such as general industry and market conditions, and changes of interest rate and currency exchange rate. These risks and uncertainties particularly apply with respect to product-related forward-looking statements. Product risks and uncertainties include, but are not limited to, completion and discontinuation of clinical trials; obtaining regulatory approvals; claims and concerns about product safety and efficacy; technological advances; adverse outcome of important litigation; domestic and foreign healthcare reforms and changes of laws and regulations. Also for existing products, there are manufacturing and marketing risks, which include, but are not limited to, inability to build production capacity to meet demand, unavailability of raw materials and entry of competitive products. The company disclaims any intention or obligation to update or revise any forward-looking statements whether as a result of new information, future events or otherwise.

For Further Information, Contact:

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References

1. Takahashi G, Asanuma F, Suzuki N. Effect of the potent and selective DP1 receptor antagonist, asapiprant (S-555739), in animal models of allergic rhinitis and allergic asthma. *Eur J Pharmacol.* 2015;765:15-23