Press Release

SHIONOGI

UBE Transform Tomorrow Today

Receives U.S. FDA Fast Track Designation
for the Novel Anti-Respiratory Syncytial Virus Drug Candidate S-337395

OSAKA, Japan, and TOKYO, Japan. October 24, 2024 - Shionogi & Co., Ltd. (Head Office: Osaka, Japan; Chief Executive Officer: Isao Teshirogi, Ph.D.; hereafter "Shionogi") and UBE Corporation (Head Office: Minato-ku, Tokyo; President & Representative Director: Masato Izumihara.; hereafter "UBE") announced that the U.S. Food and Drug Administration (FDA) has granted Fast Track designation for S-337395, our novel anti-respiratory syncytial virus (RSV) drug candidate (hereafter "S-337395").

The FDA's Fast Track designation is designed to facilitate the development and expedite the review of potential new therapies that may treat serious conditions and fulfill an unmet medical need. Respiratory infections caused by RSV are diseases that most children contract at least once by the age of two and many children continue to experience recurrent infections throughout their lives.[1] In particular, RSV often causes inflammation of the lower respiratory tract and severe respiratory symptoms in newborns, infants, and the elderly, making early treatment critically important.[2] However, effective antiviral treatment options for RSV remain limited, and there continues to be a significant unmet medical need in this area.[3]

S-337395 is an oral, novel anti-RSV investigational drug that targets the protein, essential for RSV replication, thereby inhibiting its proliferation. A dose-dependent reduction of RSV in the lungs was confirmed in non-clinical trials, and currently, a Phase 2 trial is underway to assess the efficacy and safety of S-337395. With the recent Fast Track designation, we expect more frequent consultations with the FDA and the ability to submit application materials in stages, potentially accelerating the development and review process.

Shionogi and UBE entered a strategic research collaboration for novel anti-RSV drug candidates in 2018.[4] In 2022, Shionogi and UBE reported they would be progressing S-337395 based on the results of non-clinical studies.[5] We will continue to advance the development of S-337395, combining our respective strengths and seeking to provide this compound to patients as soon as possible.

References
1. U.S. Centers for Disease Control and Prevention. Respiratory Syncytial Virus Infection (RSV). Accessed October 15, 2024. Available at: https://www.cdc.gov/rsv/causes/index.html
2. World Health Organization. Respiratory Syncytial Virus (RSV) disease. Accessed October 15, 2024. Available at: https://www.who.int/teams/health-product-policy-and-standards/standards-and-specifications/norms-and-standards/vaccine-standardization/respiratory-syncytial-virus-disease
3. Drysdale SB, Broadbent L. Respiratory syncytial virus (RSV): over 60 years of research but still so many unanswered questions. *Ther Adv Infect Dis*. 2023;10:20499361231159991. doi:10.1177/20499361231159991
4. Press release on December 10, 2018
5. Press release on February 28, 2022

【About Shionogi & Co., Ltd.】

Shionogi is committed to "Protect people worldwide from the threat of infectious diseases" as our key focus. We are not only conducting research and development of novel therapeutics, but we are also working towards total care, through building awareness, epidemiologic monitoring, prevention, diagnosis, and addressing exacerbations, as well as treating the infection itself.
For more information, please visit https://www.shionogi.com/global/en/.

【About UBE Corporation】

UBE Corporation encompasses a group of specialty chemicals businesses, of which the pharmaceuticals business comprises the core of its life sciences portfolio, progressing beyond its track record of discoveries in small molecule therapeutics into high added-value products such as ADCs (antibody-drug conjugates). Alongside is a CDMO (contract development and manufacturing organization) business, which is strengthening its existing small molecule production capacity while also acquiring capabilities in novel modalities such as oligonucleotide therapeutics. UBE's life science businesses will continue to offer solutions that enhance and protect human life and health https://www.ube.com/ube/en/

Forward-Looking Statements

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 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, lack of availability 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.

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