Press Release

About a Phase III Clinical Study of Cancer-Specific Peptide Vaccine S-588410 in Patients with Esophageal Cancer

OSAKA, Japan, July, 16, 2021 - Shionogi & Co., Ltd. (Head Office: Osaka, Japan; President and CEO: Isao Teshirogi, Ph.D. ; hereafter "Shionogi") has completed a Phase III clinical study of the cancer peptide vaccine S-588410 in patients with esophageal cancer ("the study"). The drug is licensed under an agreement with OncoTherapy Science, Inc. (Head Office: Kanagawa, Japan, President and CEO Jae-Hyun Park, hereafter "OTS").

This is a Phase III, randomized, double-blind, placebo-controlled study to assess the efficacy of S-588410 as a postoperative adjuvant therapy in patients with esophageal cancer. After evaluation of recurrence free survival (RFS), which is the time to cancer recurrence, which is the primary endpoint, no significant prolongation of RFS was found in the S-588410 group as compared with the placebo group. Regarding the secondary endpoint, induction of cytotoxic T lymphocytes (CTL), a high induction rate was found after administration of S-588410. The main adverse reaction was a skin reaction at the injection site, but no cases of serious skin reaction were observed.

Following the results of the study and various additional analyses, Shionogi will determine the future development policy for S-588410 after consultation with OTS.

Forward Looking Statement

This announcement contains forward-looking statements. These statements are based on expectations considering 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.

For Further Information, Contact:
SHIONOGI Website Inquiry Form : https://www.shionogi.com/global/en/contact.html