November 24, 2022
KANEKA CORPORATION

Kaneka to Manufacture and Supply Intermediates for Shionogi COVID-19 Drug

Kaneka Corporation (Headquarters: Minato-ku, Tokyo; President: Minoru Tanaka) will manufacture and supply intermediates to Shionogi & Co., Ltd. (Headquarters: Chuo-ku, Osaka; Chief Executive Officer: Isao Teshirogi, Ph.D.) for use in Xocova®*1 (Ensitrelvir Fumaric Acid) Tablets 125mg, a drug for the treatment of SARS-Cov-2 infection.

On November 22, Shionogi received emergency regulatory approval from the Ministry of Health, Labour and Welfare to manufacture and sell Xocova® tablets for treating SARS-Cov-2 infection. Shionogi recognized Kaneka for its long years of experience in manufacturing raw materials for medicines, and selected Kaneka as its main supplier for the drug's intermediates, which require GMP*2 management. The two companies have worked closely together for clinical development, approval application, and establishment of mass production supply chain. Kaneka will continue to improve its manufacturing systems and provide Shionogi with a stable supply of intermediates, playing a vital role in Shionogi's commercial supply chain.

Kaneka will continue to address a broad range of infection-related issues for COVID-19 and other diseases through initiatives including contract manufacturing of drug substance of DNA vaccine, development of antibody drugs, supplying PCR testing reagents and testing kits, and vaccine transportation using isothermal shipping packages. We will bring together our diverse technologies and work closely with pharmaceutical companies such as Shionogi to provide the solutions for a fight against infectious diseases.

*1. Xocova is a registered trademark of Shionogi & Co., Ltd. Ensitrelvir is an investigatio nal drug outside of Japan and has not been approved outside of Japan. In addition, the b rand name Xocova has not been approved for use outside of Japan and pertains only to t he approved drug in Japan.
*2. Good Manufacturing Practice. the guidelines for production and quality assurance to ensure that products are consistently high in quality. Authorities like Food and Drug Administration in US recommends, and manufacturers need to consider it in all the works from reception of raw materials to release of products.