



March 31, 2021

Mitsubishi Tanabe Pharma Wins Patent Infringement Lawsuit of Canagliflozin Hydrate in the U.S. District Court

Mitsubishi Tanabe Pharma Corporation (Head Office: Osaka, Japan; President & Representative Director; Hiroaki Ueno; hereafter, "MTPC") announced today that the United States District Court for the District of New Jersey ruled on March 22 local time that the U.S. Patents covering the active ingredient of canagliflozin (hereafter, "Patents") are infringed and not invalid, and the defendants' generic drug of canagliflozin hydrate (Trade Name in the U.S.: INVOKANA®/INVOKAMET®; Trade Name in Japan: CANAGLU®) shall not be approved in the U.S. earlier than July 14, 2027 (exclusivity period of 6 months may be added based on the conduct of pediatric clinical studies) .

MTPC brought patent infringement lawsuits in the U.S. concerning canagliflozin hydrate jointly with Janssen Pharmaceuticals, Inc., the holder of the new drug application for canagliflozin in the U.S. in July 2017.

The decision entered by the U.S. District Court for the District of New Jersey finds that the Patents are not invalid and would be infringed by Zydus Pharmaceuticals, Inc., who filed an Abbreviated New Drug Application (ANDA) with the U.S. Food and Drug Administration (FDA) alleging the invalidity of the Patents. Four other generic producers (Aurobindo Pharma Ltd., Invagen Pharmaceuticals, Inc., Princeton Pharmaceuticals, Inc., Sandoz, Inc.) who originally challenged these patents had relinquished their invalidity defenses.

Canagliflozin Hydrate is a type 2 diabetes therapeutic agent targeting sodium-glucose cotransporter 2 (SGLT2), which has been launched in the U.S. in 2013 and has been approved in about 100 countries including Japan, Europe and Australia.

MTPC sees intellectual property as one of its most important corporate assets and intends to take appropriate legal actions against infringements or the risk of infringement of our intellectual property in the future.

**Mitsubishi Tanabe Pharma Corporation
Corporate Communications Department**

Media contacts: TEL:+81 6 6205 5119