Mochida Filed a Partial Change Application in Approved Matters of Ulcerative Colitis Treatment LIALDA® to Add Dosage and Administration for Pediatric Patients in Japan

This material is an English translation of the press release to be issued on July 22, 2024 in Japanese, and the Japanese release is given priority regarding content and interpretation.

July 22, 2024

Mochida Pharmaceutical Co., Ltd.

Mochida Pharmaceutical Co., Ltd. (Head office: Tokyo, Japan, President: Naoyuki Mochida, hereinafter: Mochida) announced that today Mochida filed a partial change application in approved matters of ulcerative colitis treatment LIALDA® (generic name: mesalazine, development code: MD-0901, hereinafter: the product) to add dosage and administration for pediatric patients, to the Japanese Ministry of Health, Labour and Welfare (MHLW).

Mochida obtained the distribution rights for the product from Shire Pharmaceuticals Group in 2009※1and has been marketing it in Japan as a treatment for ulcerative colitis since 2016. By MMX® technology※2, the product is designed to continuously release mesalazine, the active ingredient, to and throughout the colon which is the target site. This allows the product to be once-daily oral administration in both active and remission phases of ulcerative colitis.

Mochida will make effort to obtain approval so that it can contribute to improving the quality of life of pediatric patients with ulcerative colitis.

※1The License Agreement for the product was transferred to Takeda Pharmaceuticals U.S.A., Inc. in 2023.
※2MMX® technology is a drug delivery system (DDS) designed to achieve sustained release of active ingredient to and throughout the colon.