Press Release

ASKA Pharmaceutical Holdings Co., Ltd.

ASKA Pharmaceutical Files an Application for Partial Change of Manufacturing and Marketing Approval for RIFXIMA® TABLETS (Rifaximin)

TOKYO, June 22, 2023 – ASKA Pharmaceutical Co., Ltd. (Head Office: Minato-ku, Tokyo/ President, Representative Director: Sohta Yamaguchi, hereinafter referred to as "ASKA"), a subsidiary of ASKA Pharmaceutical Holdings Co., Ltd. announces that ASKA has filed an application for partial change of the manufacturing and marketing approval of RIFXIMA® TABLETS (generic name: rifaximin, hereinafter "the Product") for additional dosage and administration for pediatric patients for the improvement of hyperammonemia in hepatic encephalopathy.

Hepatic encephalopathy is a severe complication of hepatic dysfunction, such as hepatitis and cirrhosis, and is mainly associated with neuropsychiatric symptoms. Among the various factors contributing to the onset of hepatic encephalopathy, it is believed that the increased blood concentration of ammonia, a breakdown product of intestinal bacteria from dietary protein, negatively affects neurological functions.

Ammonia produced in the gastrointestinal tract is absorbed and metabolized by the liver, but in patients with hepatic insufficiency, ammonia levels in the blood increase, and brain function declines, causing various neuropsychiatric symptoms (impaired consciousness and behavioral abnormalities). Continued hepatic dysfunction can lead to coma, which can be life-threatening.

The Product is a poorly absorbable rifamycin antimicrobial agent discovered and developed by Alfasigma S.p.A. (Head Office: Bologna, Italy) and in-licensed by ASKA. In September 2016, ASKA received manufacturing and marketing approval for the indication of "improvement of hyperammonemia in hepatic encephalopathy."

ASKA has conducted domestic clinical trials in pediatric patients with hepatic encephalopathy, and based on the results of the trials, ASKA has filed this application for partial change of the manufacturing and marketing approval items.

The Japanese Society for Pediatric Gastroenterology, Hepatology and Nutrition has submitted a request for approval of this Product's pediatric dosage and administration to the Ministry of Health, Labour and Welfare.

ASKA will continue its efforts to obtain approval to provide a new treatment option for patients and medical professionals.

Media Contacts
ASKA Pharmaceutical Holdings Co., Ltd.
Corporate Planning Department
Tel: +81-3-5484-8366
Email: kouhou@aska-pharma.co.jp