Press Release

ASKA Pharmaceutical Holdings Co., Ltd.

ASKA Pharmaceutical Receives Approval for Partial Change of Manufacturing and Marketing Approval for RIFXIMA® TABLETS (Rifaximin) for Pediatric Indication

TOKYO, March 26, 2024 – 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. (TSE:4886), announced that ASKA received approval for partial change of the manufacturing and marketing approval of RIFXIMA® TABLETS (generic name: rifaximin, hereinafter "the Product") for the pediatric indication for the improvement of hyperammonemia in hepatic encephalopathy.

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

Overview of approval

(The information related to this approval is as underlined below.)

Product name:	RIFXIMA® TABLETS 200mg
Generic name:	Rifaximin
Indications:	Improvement of hyperammonemia in hepatic encephalopathy
Dosage and Administration:	The usual oral dosage for adults and children is 400 mg of rifaximin three times daily immediately after meals.

ASKA expects that this Product will provide a new treatment option for patients and medical professionals and contribute to the improvement of their quality of lives.

About RIFXIMA® TABLETS

The Product functions by exerting an antibacterial effect on the intestinal microflora. Even when taken orally, it is hardly absorbed into the body and suppresses ammonia-producing bacteria in the digestive tract. As a result, it is effective against hepatic encephalopathy by inhibiting the increase in blood ammonia concentration, which is considered to be a major factor in hepatic encephalopathy.

About 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.

When the liver is functioning normally, it metabolizes ammonia. However, if liver function declines due to cirrhosis or other causes, ammonia metabolism becomes inadequate, leading to increased ammonia concentration in the blood. This can result in decreased brain function and various neuropsychiatric symptoms. Hepatic encephalopathy is characterized by impaired consciousness and behavioral abnormalities, and in severe cases, it may progress to coma, which can be life-threatening.

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