Mochida obtains marketing approval for LIALDA®, a Once-Daily Treatment for Ulcerative Colitis, in Japan

This material is an English translation of the press release issued on September 28, 2016 in Japanese, and the Japanese release is given priority regarding content and interpretation.

September 28, 2016

Mochida Pharmaceutical Co., Ltd. (Head office: Tokyo, Japan, President : Naoyuki Mochida, hereinafter : Mochida) announced that the company obtained marketing approval for LIALDA® Tab. 1200mg (generic name: mesalazine), for the treatment of patients with ulcerative colitis from the Japanese Ministry of Health, Labour and Welfare (MHLW) .

LIALDA® is a new DDS formulation* of mesalazine. The drug is designed to continuously release the medication to and throughout the colon (the site of inflammation in ulcerative colitis), and is approved as a once-daily oral treatment in both active and remission phases of ulcerative colitis. It has been approved in 37 countries since 2007, when it was first launched with the brand name “LIALDA®”in the U.S.
Mochida has developed LIALDA® in Japan under a License Agreement implemented in 2009 with Shire Pharmaceuticals Group, a subsidiary of Shire plc (Headquarters: Dublin, Ireland; Chief Executive Officer: Flemming Ornskov).

Mochida believe that LIALDA® will contribute to improving the Quality of Life of patients with ulcerative colitis as a new therapeutic option. Expected launch date will be announced at the NHI Price Listing.

Mochida expects that this will have only a minor impact on its near-term earnings.

* This DDS formulation utilizes MMX® technology developed by Cosmo Pharmaceuticals NV (Headquarters: Dublin, Ireland).

Summary of the marketing approval

Brand name	:	Lialda tablet 1200 mg
Generic Name	:	Mesalazine
Ingredients and Contents	:	Each tablet contains 1200 mg mesalazine.
Indication	:	Ulcerative colitis (excluding severe cases)
Dosage and Administration	:	The usual oral dosage of this product in adults is 2,400 mg of mesalazine once daily after meals. In the active stage, the oral dosage of this product in adults is 4,800 mg of mesalazine once daily after meals. The dosage may be reduced according to patient’s age and symptoms.
Approved Date	:	September 28, 2016