Mochida files New Drug Application for MD-0901, a Once-Daily Treatment for Ulcerative Colitis, in Japan

This material is an English translation of the press release issued on October 30, 2015 in Japanese, and the Japanese release is given priority regarding content and interpretation.

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Mochida Pharmaceutical Co., Ltd. (Head office: Tokyo, Japan, President : Naoyuki Mochida, hereinafter : Mochida) announced that the company filed a new drug application (NDA) for MD-0901, for the treatment of patients with ulcerative colitis with the Japanese Ministry of Health, Labour and Welfare (MHLW) .

MD-0901 is once-daily oral formulation of mesalazine (5-aminosalicylic acid, 5-ASA), which is designed to release the medication to and throughout the colon (the site of the inflammation in ulcerative colitis). It has been approved in 37 countries since 2007, when it was first launched with its brand name “LIALDA®”in the U.S.
Mochida has developed MD-0901 in Japan under a License Agreement with Shire Pharmaceuticals Group, a subsidiary of Shire plc (Headquarters: Dublin, Ireland; Chief Executive Officer: Flemming Ornskov) executed in 2009.

Ulcerative colitis is an inflammatory disease that causes erosion and ulcers on the large intestine mucosa. A lesion of it is originally formed in the rectum and extends toward the colon. Frequent diarrhea with possible bleeding and spastic abdominal pain are characteristic symptoms of it. Severe cases of it show systemic symptoms such as fever, body weight loss, and anemia. It is an intractable disease with the repetition of remissions and exacerbation. The number of ulcerative colitis patients in Japan is estimated to be 150,000 or more.
Mochida will make the utmost effort to obtain the approval for MD-0901 and contribute to supporting patients with ulcerative colitis in Japan.

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