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Mochida seeks Ulcerative Colitis drug approval in Japan

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Tokyo's Mochida Pharmaceutical Co. Ltd. has filed for a new drug application (NDA) for MD-0901 with the Japanese Ministry of Health, Labour and Welfare (MHLW). MD-0901 is indicated for the treatment of patients with ulcerative colitis.

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 US.

Mochida has developed MD-0901 in Japan under a License Agreement with Shire Pharmaceuticals Group, a subsidiary of Dublin-headquartered Shire plc.

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.