MOCHIDA PHARMACEUTICAL CO.,LTD.

June 24, 2025

Mochida Pharmaceutical Co., Ltd.

# Mochida Obtained Approval for a Partial Change Application in Approved Matters of Ulcerative Colitis Treatment LIALDA to Add Dosage and Administration for Pediatric Patients and Obtained Marketing Approval for LIALDA Tablets 600mg

Mochida Pharmaceutical Co., Ltd. (Head office: Tokyo, Japan, President: Naoyuki Mochida, hereinafter: Mochida) announced that today Mochida obtained approval for a partial change application in approved matters of ulcerative colitis treatment LIALDA (generic name: mesalazine, development code: MD-0901, hereinafter: the product) to add dosage and administration for pediatric patients and obtained marketing approval for LIALDA Tablets 600mg, from the Japanese Ministry of Health, Labour and Welfare (MHLW).

By MMX® technology[1)], the product is one of 5-aminosalicylic acid preparations designed to continuously release the active ingredient to and throughout the colon which is the target site. This allows the product to be once-daily oral administration in both active and remission phases of ulcerative colitis. Mochida in-licensed the product from Shire Pharmaceuticals Group in 2009[2)] and has been marketing it in Japan as a treatment for ulcerative colitis since 2016.

Pediatric ulcerative colitis presents clinical symptoms similarly to those in adults, but it tends to progress rapidly, with a higher likelihood of disease expansion and severe illness compared to adults, which necessitates proactive treatments[3)]. With the addition of dosage and administration for pediatric patients for the product, Mochida believes that it will provide a new treatment option for pediatric patients with ulcerative colitis.

Moreover, LIALDA Tablets 600mg have been developed, being smaller and more flexible in dosing options based on weight than LIALDA Tablets 1200mg.

Mochida believes that the product will contribute to improving the quality of life of pediatric patients with ulcerative colitis.

1) MMX® technology is a drug delivery system (DDS) designed to achieve sustained release of active ingredient to and throughout the colon.
2) The License Agreement for the product was transferred to Takeda Pharmaceuticals U.S.A., Inc. in 2023.
3) Diagnostic criteria and treatment guidelines for ulcerative colitis and crohn's disease, revised FY 2024. Research on intractable inflammatory bowel diseases (Hisamatsu group), Research program on rare and intractable diseases, Health, Labour and Welfare Sciences Research Grants.

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[References]

Summary of the approvals
(Underlined parts indicate the items approved this time)

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| Brand Name | : | LIALDA Tablets 1200mg<br>LIALDA Tablets 600mg | |
| Generic Name | : | mesalazine | |
| Ingredients and Contents | : | Film-coated Tablet<br>1200mg mesalazine per tablet<br>600mg mesalazine per tablet | |
| Indications | : | 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 patients' age and symptoms.<br>The usual oral dosage of this product in pediatric patients weighing over 23 kg is 40 mg/kg of mesalazine once daily after meals. The maximal dose should be 2,400 mg per day. In the active stage, the oral dosage of this product in pediatric patients weighing over 23 kg is 80 mg/kg of mesalazine once daily after meals. The maximal dose should be 4,800 mg per day. The dosage may be reduced according to patients' age and symptoms. | |
| Approved Date | : | LIALDA Tablets 1200mg<br>LIALDA Tablets 600mg | September 28, 2016<br>June 24, 2025 |

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