

Company name : KYORIN Holdings, Inc.
Representative Director, President : Minoru Hogawa
Securities Code : 4569, TSE 1st Sec.

**Approval received for PENTASA[®] Granules 94%,
a treatment for Ulcerative Colitis and Crohn's Disease**

TOKYO, Japan (August 17, 2015) — Kyorin Pharmaceutical Co., Ltd. (“Kyorin”) (Head office: Chiyoda-ku, Tokyo, President: Mitsutomo Miyashita), a wholly owned subsidiary of KYORIN Holdings, Inc., announced that Ulcerative Colitis and Crohn's Disease treatment drug of “PENTASA[®] Granules 94%” (INN: Mesalazine), received marketing authorization from the Ministry of Health, Labour and Welfare (“MHLW”) on August 17.

Kyorin Pharmaceutical has contributed to the treatment of inflammatory bowel diseases (ulcerative colitis and Crohn's disease) through the launch of mesalazine formulations such as Pentasa[®] Tablets (250 mg), Pentasa[®] Tablets (500 mg), Pentasa[®] Enema (1 g), and Pentasa[®] Suppositories (1 g). Recently, Kyorin developed Pentasa[®] Granules 94% using for the first time its own technology in the country, and has gained approval for this new drug. Pentasa[®] Granules 94%, which contains a large amount of mesalazine, is a new dosage designed to satisfy therapeutic needs.

Inflammatory bowel diseases are intractable diseases that hinder social interaction, causing frequent diarrhea and melena. The causes have not been identified and there is no radical treatment. Therefore, the therapeutic goals are suppressing symptoms in the active phase, alleviating the symptoms and keeping the symptoms in a relieved state with the use of mesalazine drugs like Pentasa and steroids. The recently approved drug is a useful granular agent for patients who have difficulty taking pills. A dose of Pentasa[®] Granules 94%, which contains a large amount of mesalazine, may be orally given with a single stick (maximum of 2,000 mg of mesalazine), eliminating the need to take multiple mesalazine pills when a large amount of mesalazine is required per dose. We believe these advantages will help ease the burden of patients taking oral medication and lead to improvements in medication adherence¹.

Pentasa[®] is developed by the Swiss company Ferring, and the tablet form of this drug has been approved in 107 countries for use in treating inflammatory bowel diseases. Granules has been approved in 82 countries worldwide, and is extensively used as the standard treatment for inflammatory bowel diseases.

Kyorin Pharmaceutical has added Pentasa[®] Granules 94% to its existing lineup of dosage forms. Moving forward, it will continue to provide the latest information as it works to support the treatment of patients with inflammatory bowel disease. The timing of the launch and sales projection will be announced at an appropriate time after the NHI price is listed.

¹ adherence : While compliance implies that patients follow the instructions of physicians and pharmacists, adherence means that patients should proactively take part in decisions regarding their treatment plans and receive treatment accordingly.

〈Product information〉

1. Brand name	PENTASA [®] Tablets 250 mg	PENTASA [®] Tablets 500mg	PENTASA [®] Granules 94%
2. Active ingredient	Mesalazine		
3. Indications	Ulcerative colitis (excluding severe cases), and Crohn's disease		
4. Dosage and administration	<p>Ulcerative colitis:</p> <p>The usual oral dosage of this product in adults is 1,500 mg of mesalazine daily in three divided doses after meals, in the remission stage, however, this product may be administered once daily, as required. The dosage may be adjusted according to patients' ages and symptoms, with the upper limit of 2,250 mg daily. In the active stage, however, this product may be administered in a daily dose of 4,000 mg in two divided portions, as required. The usual oral dosage of this product in children is 30 to 60 mg/kg of mesalazine daily in three divided doses after meals. The dosage may be adjusted according to patients' ages and symptoms, with the upper limit of 2,250 mg daily.</p> <p>Crohn's disease:</p> <p>The usual oral dosage of this product in adults is 1,500 to 3,000 mg of mesalazine daily in three divided doses after meals. The dosage may be reduced according to patients' ages and symptoms. The usual oral dosage of this product in children is 40 to 60 mg/kg of mesalazine daily in three divided doses after meals. The dosage may be adjusted according to patients' ages and symptoms.</p>		
5. Packaging	<p>PTP:</p> <p>100 tablets (10 tablets × 10)</p> <p>500 tablets (10 tablets × 50)</p>	<p>PTP:</p> <p>100 tablets (10 tablets × 10)</p> <p>500 tablets (10 tablets × 50)</p>	<p>Boxes of 100 packets</p> <p>(250mg※×100 packets)</p> <p>(500mg※×100 packets)</p> <p>(1000mg※×100 packets)</p> <p>(2000mg※×100 packets)</p> <p>※Mesalazine</p>

〈For Reference〉

1. Brand name	PENTASA [®] Suppositories 1g
2. Indications	Ulcerative colitis (excluding severe cases)
3. Dosage and administration	In general, one suppository (1 g of mesalazine) daily is rectally administered to adults.
4. Packaging	SP package: 50 suppositories (10 suppositories × 5), 100 suppositories (10 suppositories × 10)

1. Brand name	PENTASA [®] Enema 1g
2. Indications	Ulcerative colitis (excluding severe cases)
3. Dosage and administration	In general, the entire amount (1 g of mesalazine) of this product in a container is rectally administered once a day to adults. The dosage may be reduced according to patients' ages and symptoms.
4. Packaging	100mL×7