

Announcement of an approval for an additional indication for the Anti-depressant, Lexapro® Tablets 10 mg in Japan

Mochida Pharmaceutical Co., Ltd.
Mitsubishi Tanabe Pharma Corporation

(Tokyo, November 20, 2015) We, Mochida Pharmaceutical Co., Ltd. (Head office: Tokyo, Japan, President: Naoyuki Mochida, hereinafter referred to as: "Mochida") and Mitsubishi Tanabe Pharma Corporation (Head office: Osaka, Japan, President: Masayuki Mitsuka, hereinafter referred to as: "Mitsubishi Tanabe Pharma"), are pleased to announce that Mochida has received the approval of an additional indication, social anxiety disorder (SAD), for Lexapro® Tablets 10 mg (generic name: escitalopram oxalate, hereinafter referred to as: "Lexapro®") from the Japanese Ministry of Health, Labour and Welfare (MHLW) on November 20, 2015.

Lexapro® is a selective serotonin reuptake inhibitor (SSRI) antidepressant originated by H. Lundbeck A/S (Head office: Copenhagen, Denmark; President & CEO: Kåre Schultz; hereinafter: "Lundbeck"). Mochida started the development in Japan under a license from Lundbeck in 2002, obtained the manufacture and marketing approval of Lexapro® with the indication for treatment of depression/depressive state in 2011, and launched it in August that year. The marketing has been conducted under the framework consisting of a co-marketing with Mitsubishi Tanabe Pharma and a joint promotion with Yoshitomiyakuhin Corporation (Head office: Chuo-ku, Osaka-shi; President: Naoyuki Kishi).

SAD is an anxiety disorder characterized by intense fear or excessive anxiety in social situations such as possible exposure to attention from others. Patients with SAD are so afraid of these situations that they try to avoid them, resulting in interference in their activities of daily life. We hope that Lexapro® will contribute to improving the QOL of the patients with SAD as a new therapeutic option in Japan.

The impact of the approval on the consolidated financial results of Mochida and Mitsubishi Tanabe Pharma will be minor for the near term.

Summary of the marketing approval

The underlined part has been added.

Brand Name : Lexapro® Tablets 10mg
Generic Name : Escitalopram oxalate
Ingredients and Contents : 12.77mg Escitalopram oxalate per tablet (10mg Escitalopram per tablet)
Indication : Depression and depressed state
Social anxiety disorder
Dosage and Administration : The usual adult dose is 10 mg dose as escitalopram once a day orally after the evening meal. The dose may be adjusted as appropriate depending on the patient's age and symptoms, but dose escalation should only be carried out after a minimum of 1 week or longer, and the maximum daily dose should not exceed 20 mg.
Marketing Authorization Holder : Mochida Pharmaceutical Co., Ltd.