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Application filed for Orally Disintegrating Tablet of imidafenacin (INN), a Drug for Overactive Bladder

Ono Pharmaceutical Co., Ltd. ("Ono") (Osaka, Japan, President: Gyo Sagara) and Kyorin Pharmaceutical Co., Ltd. ("Kyorin") (Tokyo, Japan, President: Keiji Hirai, Ph.D.), a wholly owned subsidiary of Kyorin Co., Ltd. jointly announced that each company filed a new drug application for orally disintegrating tablet of imidafenacin (INN), a drug for the treatment of overactive bladder on December 24, 2009. It was originally launched in June 2007 as Staybla Tablets 0.1mg (by Ono) or Uritos Tablets 0.1mg (by Kyorin) in a form of conventional film coating tablets.

Imidafenacin is a drug that was discovered by Kyorin and co-developed by Ono and Kyorin. It is a novel anticholinergic agent exerting selective antagonist activity on M3 and M1 muscarinic subtype receptors, and improves urgency of urination, pollakiuria and urge urinary incontinence associated with OAB. It has been highly regarded that the drug can improve the quality of life (QOL) of the patients with OAB because it selectively acts on the bladder and therefore incidence of dry mouth is rather small.

The orally disintegrating tablet can be taken without water and is useful even in elderly patients, those with impaired swallowing function and those abstaining from water intake. It is expected that it can offer an additional treatment option on taking the drug and therefore contribute to the improvement of patient compliance.

Overactive bladder (OAB)

Overactive bladder (OAB) is a urological condition with trouble in pooling urine in the bladder. Its predominant symptom is an urge to urinate, which is often accompanied by frequent urination and nocturia, and in some cases by urge urinary incontinence. One of the major problems of OAB is the fact that patients refrain from leaving the house due to anxiety about going to the bathroom, cannot get enough sleep at night, or face limitations in their daily activities, which could lead to significantly-reduced quality of life. According to the epidemiological investigation of Neurogenic Bladder Society, it is estimated that approximately 8.1 million people or 12.4% of male and female over the age of 40 years potentially suffers from OAB in Japan.