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Approval Received for Orally Disintegrating Tablet of imidafenacin (INN), a Drug for Overactive Bladder

Ono Pharmaceutical Co., Ltd. (Osaka, Japan) and Kyorin Pharmaceutical Co., Ltd. (Tokyo, Japan), a wholly owned subsidiary of KYORIN Holdings, Inc., jointly announced that a new drug application filed in December 2009 for orally disintegrating (OD) tablet of imidafenacin (INN), a drug for the treatment of overactive bladder (OAB) was approved in Japan on November 9, 2010. 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, and later new dosage regimen was also approved in December 2009.

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 OD 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.

This new formulation of the product will be launched as Staybla[®] OD Tablets 0.1mg (by Ono) or Uritos[®] OD Tablets 0.1mg (by Kyorin). The timing of the launch and sales projection will be announced at an appropriate time after the NHI price is listed.

PRODUCT SUMMARY:

Product Name	Staybla [®] OD Tablets 0.1mg (by Ono) or Uritos [®] OD Tablets 0.1mg (by Kyorin)
Generic Name (INN)	Imidafenacin
Indication	Urgency of urination, pollakiuria and urge urinary incontinence associated with OAB
Dosage and Administration	Usually, for adults, a single dose of 0.1mg as imidafenacin is orally administered, twice daily, after each meal in the morning and evening. If the desired efficacy is not observed a single dose can be increased up to 0.2mg (0.4mg daily).

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 (2003), 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.