KYORIN Holdings, Inc.

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Release of "Uritos" OD Tablets 0.1mg" a Drug for Overactive Bladder

Kyorin Pharmaceutical Co., Ltd. (Tokyo, Japan), a wholly owned subsidiary of KYORIN Holdings, Inc. announced

the release of "Uritos $^{@}$ OD Tablets 0.1mg" (INN:Imidafenacin), an orally disintegrating (OD) drug for the treatment

of overactive bladder (OAB). It was originally launched in June 2007 as Uritos® Tablets 0.1mg 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 Kyorin and Ono Pharmaceutical Co.,

Ltd. (Osaka, Japan). 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 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 Uritos[®] OD Tablets 0.1mg (by Kyorin) or Staybla[®] OD

Tablets 0.1mg (by Ono). The sales forecast of "Uritos (Uritos® Tablets 0.1mg and Uritos® OD Tablets 0.1mg)"

for fiscal year 2011 will be disclosed at the announcement of financial results for fiscal year 2010 on May 11.

PRODUCT SUMMARY:

Uritos® OD Tablets 0.1mg Product Name

Generic Name (INN) Imidafenacin

Indication Urgency of urination, pollakiuria and urge urinary incontinence associated with OAB

Dosage and Usually, for adults, a single dose of 0.1mg as imidafenacin is orally administered, twice Administration

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).

Date of Approval November 9,2010

Date of Drug Price

Listing

March 18,2011

Date of initial marketing in Japan:

PACKAGING

April 4,2011

PTP 100,500 tablets

NHI PRICE ¥96.50 per tablet

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.