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## **Launch of Staybla<sup>®</sup> Tablets 0.1mg, a Drug for Overactive Bladder**

Ono Pharmaceutical Co., Ltd. (Osaka, Japan, President: Toshiharu Korekane) announced that the company launched Staybla<sup>®</sup> Tablets 0.1mg (imidafenacin), a Drug for treatment of Overactive Bladder (OAB) today.

OAB is a condition based on excessive contraction of bladder smooth muscle. It mainly causes urgency of urination which is usually accompanied by pollakiuria and nocturia and in some cases by urge urinary incontinence. Contraction of bladder smooth muscle causing OAB is controlled mainly via muscarinic receptor, and therefore it has been said that anticholinergic drugs exerting antagonist activity on muscarinic receptor are effective for the OAB treatment. However at the same time it is possible that adverse drug reactions based on the pharmacological actions such as dry mouth intervene in continuation of the drug treatment.

Staybla<sup>®</sup> Tablets 0.1mg is a drug that was discovered by Kyorin Pharmaceutical Co., Ltd. and co-developed by Kyorin and Ono. It is a novel anticholinergic agent exerting selective antagonist activity on M<sub>3</sub> and M<sub>1</sub> muscarinic subtype receptors, and improves urgency of urination, pollakiuria and urge urinary incontinence associated with OAB. It is expected that this drug can contribute to improvement of the patient QOL of OAB because it selectively acts on the bladder and therefore incidence of dry mouth would be rather small.

Ono will strive to actively provide the scientific information for proper use of Staybla<sup>®</sup> Tablets 0.1mg and to pursue the market penetration as early as possible through co-marketing with Kyorin.

For more information, please refer to the product profile in the next page.

## < PRODUCT PROFILE >

Trade name	Staybla <sup>®</sup> Tablets 0.1mg
Nonproprietary name	Imidafenacin
Indications	Urgency of urination, pollakiuria and urge urinary incontinence associated with OAB
Dosage and administration	Usually, for adults, a Staybla <sup>®</sup> tablet is orally administered in a single dose of 0.1mg as imidafenacin, twice daily, after each meal in the morning and evening.
Features	<ol style="list-style-type: none"><li>1) Twice daily treatment with a Staybla<sup>®</sup> 0.1 mg tablet improves urgency of urination, pollakiuria and urge urinary incontinence associated with OAB.</li><li>2) It selectively acts on the bladder comparing to its action on the salivary gland in rats.</li><li>3) It exerts selective antagonist activity on M<sub>3</sub> and M<sub>1</sub> muscarinic subtype receptors, and inhibits contraction of bladder smooth muscle and acetylcholine release (<i>in vitro</i>).</li><li>4) Rate of discontinuation of the drug treatment due to adverse drug reactions is 4.6% in clinical studies (54 out of 1,172 patients at the time that it is approved).</li></ol>
NHI price	0.1 mg tablet : JPY 100.80
Packaging	Boxes of 100 and 500 tablets in press-through package Bottles of 500 tablets
Date of NHI price listing	June 8, 2007
Date of launch	June 11, 2007