



FOR IMMEDIATE RELEASE

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KYORIN Holdings, Inc.
Eisai Co., Ltd.

KYORIN and Eisai Enter Into License Agreement Concerning the Development and Marketing of Vibegron, a Treatment for Overactive Bladder, in Four ASEAN Countries

KYORIN Pharmaceutical Co., Ltd. (Headquarters: Chiyoda-ku, Tokyo, President and CEO: Shigeru Ogihara, "KYORIN"), a subsidiary of KYORIN Holdings, Inc. (Headquarters: Chiyoda-ku, Tokyo, President and CEO: Yutaka Ogihara), and Eisai Co., Ltd. (Headquarters: Bunkyo-ku, Tokyo, CEO: Haruo Naito, "Eisai") have entered into a license agreement for development and distribution of vibegron, a therapeutic agent for overactive bladder, in four ASEAN (Association of Southeast Asian Nations) member states; Thailand, the Philippines, Malaysia and Brunei. Based on this agreement, Eisai will acquire exclusive development and marketing rights from KYORIN for the agent in the said four countries, and will be responsible for submitting a New Drug Application for the agent.

Overactive bladder (OAB) is the name for a group of urinary symptoms characterized by urinary urgency, usually accompanied by increased daytime frequent urination and/or nocturia, and in some cases by urge urinary incontinence. OAB has a detrimental impact on patient health-related QOL (quality of life), interfering with the patients' daily life such as preventing them from going out due to anxiety that they often go to the bathroom due to OAB, and reducing quality of sleep.

This agent is a novel β_3 -adrenergic receptor agonist administered once daily, acting selectively on β_3 receptors in the bladder, relaxing the bladder to enhance urine collection, and consequently improving the symptoms of urgency, urinary frequency and urge urinary incontinence associated with OAB.

KYORIN has been making a contribution to improving the quality of life of patients with OAB through early penetration of the agent into the Japanese market. With the execution of this agreement, KYORIN will now work with Eisai to make the agent available in the licensed territory and promote the expansion of its business internationally.

Eisai is making efforts to determine and meet the diversified needs of each market in the licensed territory, and will continue to actively expand and enrich its strategic product portfolio to match the needs of the region.

In September 2009, KYORIN and Eisai signed a license agreement for the development and marketing in Asia of Uritos® Tablets (generic name: imidafenacin), a therapeutic agent for overactive bladder, discovered and developed by KYORIN, and as of today Eisai sells Uritos in Thailand, the Philippines, Indonesia and Myanmar. By developing and commercializing vibegron in addition to Uritos, the two companies will provide patients with new treatment options for OAB and make further contributions to improving the quality of life and increasing benefits to patients with OAB.

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<Notes to editors>

1. About KYORIN Pharmaceutical Co., Ltd.

KYORIN is working to improve its presence in specific areas and create new drugs globally with the aim of becoming a pharmaceutical manufacturer whose significance is recognized by society, and that is trusted by patients and those involved in medical care. In terms of sales, KYORIN is enhancing an FC (franchise customer) strategy that focuses on users, mainly in the respiratory, otolaryngology, and urology departments. In drug discovery, KYORIN is developing its activities for first-in-class drug discovery, such as promoting selection and concentration, working on developing a multi-layered program, and actively exploring and installing external drug discovery themes.

For more information on KYORIN Pharmaceutical Co., Ltd., please visit <https://www.kyorin-pharm.co.jp/en/>.

2. About Eisai Co., Ltd.

Eisai Co., Ltd. defines our corporate mission as "giving first thought to patients and their families and to increasing the benefits health care provides," which we call our *human health care (hhc)* philosophy. With approximately 10,000 employees working across our global network of R&D facilities, manufacturing sites and marketing subsidiaries, we strive to realize our *hhc* philosophy by delivering innovative products to address unmet medical needs, with a particular focus in our strategic areas of Neurology and Oncology. As a global pharmaceutical company, our mission extends to patients around the world through working with key stakeholders to improve access to medicines in developing and emerging countries.

For further information on Eisai Co., Ltd., please visit <https://www.eisai.com>.

3. About Vibegron

Vibegron was discovered by Merck & Co., Kenilworth, N.J., U.S.A. (known as MSD outside of the United States and Canada) as a once-daily oral treatment for overactive bladder (OAB), which acts selectively on the bladder's β_3 -adrenergic receptor agonists. Vibegron selectively acts on β_3 receptors in the bladder and increases bladder capacity by enhancing the bladder-relaxing effect of noradrenaline during the urinary storage phase, resulting in the improvement of incontinence symptoms of urinary urgency, frequent urination and urge urinary incontinence with OAB. KYORIN has obtained exclusive rights for developing, manufacturing and marketing of this drug in Japan (July 2014) and Asia* (April 2017) from Merck & Co., Inc. Kenilworth, N.J., U.S.A. In Japan, KYORIN and Kissei have jointly developed the agent locally under a co-development and co-marketing agreement entered into as of March 2016. Since November 2018, the two companies have been jointly marketing it under the product name of "Beova[®] Tablets 50mg".

*South Korea, Taiwan, Hong Kong, and 10 member states of ASEAN

4. About Overactive Bladder (OAB)

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.

In general, it is said that the total number of patients with OAB increases with aging. In Asia, although the actual number of patients is unknown, it has been reported among adults over the age of 18 that 29.9% of men and 34.7% of women experience some form of OAB.¹

1. *J Med Assoc Thai*. 2007; 90 (11): 2316-20