May 7, 2026

Company:	KYORIN Pharmaceutical Co., Ltd.
Representative:	Yutaka Ogihara Representative Director, President and CEO (Security Code: 4569, TSE Prime.)
Contact:	Shota Kikuchi Director, Corporate Planning
Telephone:	03-6374-9702

Notice Regarding the Initiation of a Phase 3 Clinical Trial for Overactive Bladder Treatment "Vibegron" (Development Code: KRP-114VP)

KYORIN Pharmaceutical Co., Ltd. announced today that it has initiated a Phase 3 clinical trial of the overactive bladder (OAB) treatment "Vibegron".

The Phase 3 clinical trial is a multicenter, randomized, double-blind, placebo-controlled study to evaluate the efficacy and safety of Vibegron administered for 8 weeks to pediatric patients with OAB, aiming to expand the indication of "Beova® Tablets 50mg" to pediatric use.

Vibegron is a selective β3-adrenergic receptor agonist. It acts selectively on β3 receptors in the bladder, relaxing the bladder to enhance urine storage function, and consequently improving the symptoms of urgency, urinary frequency and urge urinary incontinence associated with OAB. In Japan, it is currently marketed as "Beova® Tablets 50mg" for the treatment of OAB in adults.

Currently, no drugs in Japan have a pediatric indication for OAB. By developing Vibegron, KYORIN aims to provide a new treatment option for pediatric OAB patients.

The impact on business performance for the fiscal year ending March 2027 is expected to be negligible.

[Reference]

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. In children, OAB is also said to significantly impact self-esteem.

About Vibegron

Vibegron was discovered by Merck & Co., Rahway, N.J., U.S.A. (known as MSD outside of the United States and Canada) as a once-daily oral treatment for OAB, which acts selectively on the bladder's β3-adrenergic receptor agonists. Vibegron selectively acts on β3 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 Vibegron in Japan (July 2014) and Asia* (April 2017) from Merck & Co., Inc., Rahway, N.J., U.S.A.

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