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FOR IMMEDIATE RELEASE

Company: KYORIN Holdings, Inc.  
Representative: Masahiro Yamashita  
Representative Director, President  
(Securities Code: 4569, TSE 1st Sec.)

### **Kyorin signed a License Agreement with Merck on Vibegron for Overactive Bladder in Japan**

KYORIN Holdings, Inc. announced today that its wholly owned subsidiary, KYORIN Pharmaceutical Co., Ltd. ("Kyorin", Head office: Chiyoda-ku, Tokyo, President & CEO: Mitsutomo Miyashita, Ph.D.), has entered into a license agreement with Merck & Co., Inc. ("Merck", Head Office: New Jersey, U.S.A., CEO: Kenneth C. Frazier) for Merck's investigational overactive bladder (OAB) therapeutic agent, Vibegron (Merck's Development Code: MK-4618).

Under the terms of the agreement, Merck has granted to Kyorin an exclusive license to develop, manufacture and commercialize Vibegron in Japan. Kyorin will make an upfront payment and additional contingent milestone payments to Merck, including royalties on product sales.

Vibegron is a new chemical entity discovered by Merck with selective beta 3 adrenergic receptor agonist activity and is expected to be a once daily therapeutic medication in patients with OAB. Vibegron improves OAB symptoms such as urinary urgency, micturition and urge incontinence through stimulation of the beta 3 receptor in bladder which improves bladder muscle atony during the period of urine pooling. Multi-national Ph2b studies including Japan have been completed by Merck, and Kyorin is planning to proceed development in a Phase 3 study in Japan.

Kyorin has been pursuing the franchise customer strategy on the fields of respiratory, ear-nose-throat and urology and expects that this transaction will heighten its presence in the urology field. The company will complete the development of Vibegron as quickly as possible and aims for further contribution to the OAB treatments by offering a new medication option to OAB patients.

Merck is working on a global initiative to sharpen its research and development focus and has decided, in that process, to out-license Vibegron to Kyorin.

Kyorin believes that this transaction will, under the principles of contribution to people's health, further contribute to the improvement of the QOL of the patients with OAB symptoms in Japan.

Kyorin will timely disclose the impact of this transaction on earnings once details are finalized.

### **About Overactive Bladder (OAB)**

Overactive bladder is a symptom complex with a problem of bladder-storage function in which urinary urgency is observed as main complaint commonly associate with micturition and in some cases, urinary incontinence, too. OAB symptoms cause a serious problem directly linked to inferior in quality of daily life of the patient and limit the patients' work and social life. For example, patients tend to refrain from going out due to whose apprehension to urge to visit bathroom or lack of sleep by nocturia.

In accordance with the epidemiological surveillance by Japan Neurogenic Bladder Society in 2003, the number of potential patient of OAB in Japan is estimated about 810,000, which means 12.4% population in men and women who are 40 years of age or more.

### **About Merck**

Today's Merck is a global healthcare leader working to help the world be well. Merck is known as MSD outside the United States and Canada. Through its prescription medicines, vaccines, biologic therapies, and consumer care and animal health products, Merck works with customers and operate in more than 140 countries to deliver innovative health solutions. Merck also demonstrates its commitment to increasing access to healthcare through far-reaching policies, programs and partnerships. For more information, visit [www.merck.com](http://www.merck.com).