

September 21, 2018

NEWS RELEASE

KYORIN Holdings, Inc.
(Securities Code: 4569, TSE 1st Sec.)
Kissei Pharmaceutical Co., Ltd.
(Securities Code: 4547, TSE 1st Sec.)

**Kyorin Receives Marketing Approval in Japan for
"Beova[®] Tablets 50mg" for the Treatment of Overactive Bladder**

KYORIN Holdings, Inc. (Head office: Chiyoda-ku, Tokyo, President & CEO: Minoru Hogawa)and Kissei Pharmaceutical Co., Ltd. (Head office: Matsumoto-city, Nagano, Chairman and CEO: Mutsuo Kanzawa, "Kissei") jointly announced today that KYORIN Pharmaceutical Co., Ltd. (Head office: Chiyoda-ku, Tokyo, President & CEO: Minoru Hogawa, " KYORIN Pharmaceutical"), a wholly owned subsidiary of KYORIN Holdings, Inc., received approval from the Ministry of Health, Labour and Welfare as of September 21, 2018 to market "Beova[®] Tablets 50mg" ("Beova[®] Tablets") for the treatment of overactive bladder.

KYORIN Pharmaceutical signed a license agreement with Merck & Co., Kenilworth, N.J., U.S.A. (Head office: New Jersey, U.S.A., CEO: Kenneth C. Frazier) in July 2014 concerning the grant of an exclusive license to develop, manufacture and market this agent in Japan. The product has been jointly developed by KYORIN Pharmaceutical and Kissei under a co-development and co-marketing agreement entered into as of March 2016. KYORIN Pharmaceutical subsequently filed a marketing approval application for Beova[®] Tablets with the Ministry of Health, Labour and Welfare in September 2017. With successful receipt of marketing approval, Beova[®] Tablets will be co-marketed by KYORIN Pharmaceutical and Kissei.

Vibegron, an active ingredient of Beova[®] Tablets, was discovered by Merck & Co., Kenilworth, N.J., U.S.A. and developed by KYORIN Pharmaceutical and Kissei locally in Japan as a novel once-daily oral treatment for overactive bladder (OAB). Beova[®] Tablets act selectively on the bladder's β_3 -adrenergic receptor, relax the bladder and enhance the urine collection, and consequently improve the symptoms of urgency, urinary frequency and urge urinary incontinence associated with OAB.

Having the effects to improve various symptoms associated with OAB, anti-cholinergic agents have been commonly prescribed in the OAB medication in Japan, but the long-term therapeutic compliance is not sufficient because the treatment with anti-cholinergic agents sometimes discontinues due to the development of adverse reactions such as dry mouth as well as the insufficient therapeutic effects. In these circumstances, β_3 -adrenergic receptor agonists were developed as new OAB therapeutics.

While β_3 -adrenergic receptor agonists have a potential to avoid the adverse reactions of anti-cholinergic drugs, cardiovascular effects such as the increased pulse rate and the change in the blood pressure are publicly known as the adverse reactions of β_3 -adrenergic receptor agonists, and elderly patients with multiple medications need to be careful about drug-drug interactions. With the recognition that it is important to develop an easy-to-use OAB treatment with less cardiovascular effects and drug-drug interactions, KYORIN Pharmaceutical decided to develop this product.

Both KYORIN Pharmaceutical and Kissei have positioned the urology field as one of their respective strategic areas and been engaged in the expansion of product lineup and presences in that field. The companies will continuously work on the contribution to the OAB treatments by offering a new therapeutic option to the OAB patients with smooth penetration of this product into the market.

###

About Beova®

Product Name: Beova® Tablets 50mg

INN: Vibegron

Indications: Urinary urgency, urinary frequency and urge urinary incontinence associated with overactive bladder

Dosage and Administration: The usual oral dosage for adults is 50mg of vibegron once daily after meal.

About Overactive Bladder (OAB)

Overactive bladder (OAB) is a condition with the symptoms such as "urinary urgency (sudden, desire to pass urine that is difficult to defer)", "urinary frequency (the condition where urination is more often than usual)" and "nocturia" resulting from aging, neurological disorder etc.

Symptom prevalence of OAB tends to increase with advancing age, and OAB patients in Japan are estimated to be 10.4 million from the population structures in 2012*. In step with the aging of the population, OAB patients is expected to further increase, and the contribution of OAB medication to the improvement of the health including QOL is considered meaningful.

* Clinical Guidelines for Overactive Bladder Syndrome 2nd Edition, The Japanese Continence Society