



November 20, 2018

NEWS RELEASE

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

Launch of “Beova® Tablets 50mg” for the Treatment of Overactive Bladder

KYORIN Pharmaceutical Co., Ltd. (Head Office: Chiyoda-ku, Tokyo, President & CEO: Minoru Hogawa, “KYORIN”), a subsidiary of KYORIN Holdings, Inc. (Head Office: Chiyoda-ku, Tokyo, President & CEO: Minoru Hogawa), and Kissei Pharmaceutical Co., Ltd. (Head Office: Matsumoto City, Nagano, Chairman & CEO: Mutsuo Kanzawa, “Kissei”) will launch “Beova® Tablets 50mg (“Beova® Tablets”)” for the treatment of overactive bladder on November 27, 2018.

KYORIN 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 and Kissei under a co-development and co-marketing agreement entered into as of March 2016. KYORIN subsequently received manufacturing and marketing approval in September 2018, and after the NHI price listing on November 20, 2018, the drug will now be launched.

Vibegron, an active ingredient of Beova® Tablets, is a novel once-daily oral treatment for overactive bladder (OAB), acts selectively on the bladder's β_3 -adrenergic receptor, relaxes the bladder and enhances the urine collection, and consequently improves the symptoms of urgency, urinary frequency and urge urinary incontinence associated with OAB.

The characteristics of “Beova® Tablets” are as follows:

- ① Demonstrated significant improvement in OAB symptoms urinary urgency, urinary frequency, and urge urinary incontinence with once daily administration compared with the placebo group.
- ② Improved all domains on the King’s Health Questionnaire*2, an indicator of QOL.
- ③ Maintained Effects up to 52 weeks of administration.

Both KYORIN and Kissei have positioned the urology field as one of their respective strategic areas, will continuously work for OAB patients by offering this new therapeutic option with smooth penetration into the market.

*1 OAB: **O**veractive **B**ladder

*2 **K**ing’s **H**ealth **Q**uestionnaire: KHQ

A QOL questionnaire specific to urinary incontinence that is comprised of 19 items in 8 areas, and has been confirmed to also be valid for overactive bladder

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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.
NHI price : ¥ 185.70
Packaging: 100 tablets (PTP10 × 10) 、 140 tablets (PTP14 × 10)
Date of Drug Price Listing: November 20, 2018
Date of Launch in Japan: November 27, 2018

〈 **product photo**〉 Kyorin:Beova® Tablets 50mg



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