

Press Release

Addition of Mirabegron to Tamsulosin Demonstrates Superior Efficacy Compared to Placebo in Men with Overactive Bladder Symptoms

TOKYO – May 24, 2018 – Astellas Pharma Inc. (President and CEO: Kenji Yasukawa, Ph.D., “Astellas”) today announced that the post-marketing MATCH study exploring use of mirabegron versus placebo in men with overactive bladder (OAB) also taking tamsulosin for benign prostatic hyperplasia (BPH) met its primary endpoint of reducing the mean number of micturitions / 24 hours. In the study, the addition of mirabegron was well-tolerated and demonstrated superior improvement in quality of life (QoL). The data were presented at the 2018 Annual Meeting of the American Urological Association held in San Francisco.

“Through my past experiences of treating the condition, I had the impression that adding mirabegron to tamsulosin was a useful treatment. However, there was no evidence,” said Professor Hidehiro Kakizaki, Department of Renal and Urologic Surgery, Asahikawa Medical University, who presented the study results. “Therefore, it is very significant that the MATCH study, a randomized, placebo-controlled double blind study, recently proved it. I am also pleased that such evidence was obtained in Japan, where mirabegron was first commercialized. This treatment method is expected to serve as a useful treatment option for male patients with OAB symptoms following administration of tamsulosin.”

Assessed by ANCOVA (analysis of covariance), the adjusted mean change in micturitions / 24 hours from baseline to end of treatment was -1.27 in the mirabegron group vs. -0.75 for placebo, with a statistically significant adjusted mean difference between groups (-0.52 ; $P < 0.001$). Mirabegron also showed superior efficacy to placebo for increase in mean volume voided (MVV) / micturition and change in overactive bladder symptom score (OABSS) total score. Differences between mirabegron and placebo groups were not statistically significant for urgency, urgency incontinence, incontinence and nocturia episodes. For QoL, mirabegron 50 mg group demonstrated statistically significant greater improvements from baseline to the end of treatment compared with placebo group in symptom bother score by OAB-q and total health-related QoL score by OAB-q. Overall, 23.4% of mirabegron vs. 22.5% of placebo patients reported ≥ 1 treatment-emergent adverse event (TEAE). There were no significant differences in both groups for major safety concerns regarding urinary retention or cardiovascular events.

About the MATCH study

This 12-week randomized, double-blind, placebo-controlled study at sites in Japan and Korea enrolled approximately 600 male patients ≥ 40 years who still had OAB symptoms while receiving tamsulosin for BPH. After a 4-week single-blind screening period in which patients received placebo and tamsulosin, patients were randomized to mirabegron 50 mg or placebo plus tamsulosin for 12 weeks. Primary endpoint was change from baseline (BL) to end of treatment (EoT) in mean number of micturitions / 24 hours, based on a 3-day micturition diary. Safety assessments included TEAEs and laboratory data. Main secondary endpoints were change from BL to EoT in mean number of urgency, urgency incontinence and

incontinence episodes / 24 hours, and in nocturia episodes, mean volume voided (MVV)/micturition, and overactive bladder symptom score (OABSS).

For more information on the MATCH, go to www.clinicaltrials.gov.

About Benign Prostatic Hyperplasia (BPH)

Benign prostatic hyperplasia (BPH) is an enlargement of the prostate, which is situated beneath the bladder; it compresses the urethra and causes urination disorder. Based on statistics, it is known that 20 percent of Japanese men aged 55 years and older have symptoms of prostatic hyperplasia. Although symptoms vary depending on individuals, common symptoms include "Needing to go to the toilet to pass urine frequently (more than 7 times a day)," "Sudden urinary sensation which is difficult to control," "Not being able to hold on and sometimes passing urine before reaching the toilet," "Getting up to go to the toilet to pass urine during the night many times," and "Sometimes finding it difficult to pass urine." While in good health, urination is performed routinely; however, once urination is disturbed, it poses considerable obstacles to everyday life.

About Overactive Bladder (OAB)

Overactive bladder (OAB) is a urine storage problem of urgency, with or without urge urinary incontinence(leakage), often with urinary frequency and nocturia.¹ It has been estimated by this year, 546 million people worldwide will be affected by OAB.² For people with OAB, inappropriate signals are sent to the muscle in the bladder causing them to contract before the bladder is full.³ These bladder contractions may cause strong, sudden urges, and a frequent need to go to the bathroom.

About Astellas

Astellas Pharma Inc., based in Tokyo, Japan, is a company dedicated to improving the health of people around the world through the provision of innovative and reliable pharmaceutical products.

For more information, please visit our website at <https://www.astellas.com/en>

Cautionary Notes

In this press release, statements made with respect to current plans, estimates, strategies and beliefs and other statements that are not historical facts are forward-looking statements about the future performance of Astellas. These statements are based on management's current assumptions and beliefs in light of the information currently available to it and involve known and unknown risks and uncertainties. A number of factors could cause actual results to differ materially from those discussed in the forward-looking statements. Such factors include, but are not limited to: (i) changes in general economic conditions and in laws and regulations, relating to pharmaceutical markets, (ii) currency exchange rate fluctuations, (iii) delays in new product launches, (iv) the inability of Astellas to market existing and new products effectively, (v) the inability of Astellas to continue to effectively research and develop products accepted by customers in highly competitive markets, and (vi) infringements of Astellas' intellectual property rights by third parties.

Information about pharmaceutical products (including products currently in development) which is included in this press release is not intended to constitute an advertisement or medical advice.

References:

1. Abrams P, Cardozo L, Fall M, et al. The standardisation of terminology in lower urinary tract function: report from the standardisation sub-committee of the International Continence Society. *Urology* 2003;61(1):37-49.
2. Irwin DE, Kopp ZS, Agatep B, Milsom I, Abrams P. Worldwide prevalence estimates of lower urinary tract symptoms, overactive bladder, urinary incontinence and bladder outlet obstruction. *BJU Int.* 2011;108(7):1132-8.
3. Sadananda P, Drake MJ, Paton JFR, Pickering AE. A functional analysis of the influence of β 3-adrenoceptors on the rat micturition cycle. *J Pharmacol Exp Ther* 2013;347(2):506-15.

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