U.S. FDA Accepts for Review Astellas' Supplemental New Drug Application for mirabegron for Use in Combination with solifenacin succinate 5 mg for the Treatment of Overactive Bladder

If approved, the combination therapy could potentially offer a new treatment option for patients whose overactive bladder symptoms are not adequately controlled on monotherapy

Tokyo, Sept. 12, 2017 - Astellas Pharma Inc. (TSE: 4503, President and CEO: Yoshihiko Hatanaka, "Astellas") announced today that the U.S. Food and Drug Administration (FDA) has accepted for review a supplemental New Drug Application (sNDA) that seeks approval for the use of mirabegron in combination with solifenacin succinate 5 mg for the treatment of overactive bladder (OAB) with symptoms of urge urinary incontinence, urgency, and urinary frequency. The anticipated Prescription Drug User Fee Act (PDUFA) goal date for a decision by the FDA is April 28, 2018. In the United States, mirabegron and solifenacin succinate are marketed as Myrbetriq® and VESIcare®, respectively. Each is approved by the FDA as a monotherapy for the treatment of OAB with symptoms of urge urinary continence, urgency and urinary frequency.

The sNDA submission is based on data from the global Phase 3 SYNERGY I, SYNERGY II and BESIDE studies. These studies, which included more than 5,000 patients with OAB, evaluated combination therapy with mirabegron and solifenacin succinate compared with each drug as monotherapy and placebo.

"Living with overactive bladder can have a significant impact on even the simplest daily activities," said Bernhardt Zeiher, M.D., president of Development at Astellas. "Acceptance of this sNDA is an important step forward in bringing a potential new treatment option to individuals living with OAB whose symptoms may not be controlled on monotherapy."

About the SYNERGY I Trial
The Phase 3 SYNERGY I trial enrolled 6.991 patients across 435 study locations in 42 countries. The trial evaluated the efficacy and safety of combinations of mirabegron and solifenacin succinate compared with each drug as monotherapy and placebo in patients who had experienced symptoms of "wet" OAB (urinary frequency and urgency with incontinence) for at least 3 months.

About the SYNERGY II Trial
The 52-week, Phase 3 SYNERGY II trial enrolled 2,084 patients across 251 sites in 32 countries. The trial evaluated the efficacy and safety of combination of mirabegron 50 mg and solifenacin succinate 5 mg compared with each drug as monotherapy in patients who had experienced symptoms of "wet" OAB (urinary frequency and urgency with incontinence) for at least 3 months.

About the BESIDE Trial
The Phase 3b BESIDE study enrolled 3,815 patients across 281 sites in 36 countries. The trial evaluated the efficacy, safety and tolerability of mirabegron 50 mg in combination with solifenacin succinate 5 mg versus solifenacin 5mg and 10mg alone in OAB patients who had inadequate response to treatment with solifenacin succinate monotherapy.

About Overactive Bladder (OAB)
Overactive bladder is a urine storage problem of urgency, with or without urge urinary incontinence (leakage), often with urinary frequency and nocturia.[1] By 2018, an estimated 546 million people worldwide will be affected by OAB.[2] For people with OAB, inappropriate signals are sent to the muscles in the bladder causing them to contract before the bladder is full. These bladder contractions may cause strong, sudden urges, and a frequent need to go to the bathroom.[3]

Use of Myrbetriq
Myrbetriq (mirabegron) is a prescription medicine for adults used to treat OAB with symptoms of urgency, frequency and leakage.

Important Safety Information for Myrbetriq
Myrbetriq is not for everyone. Do not use Myrbetriq if you have an allergy to mirabegron or any ingredients in Myrbetriq. Myrbetriq may cause your blood pressure to increase or make your blood pressure worse if you have a history of high blood pressure. It is recommended that your doctor check your blood pressure while you are taking Myrbetriq. Myrbetriq may increase your chances of not being able to empty your bladder. Tell your doctor right away if you have trouble emptying your bladder or you have a weak urine stream.

Myrbetriq may cause allergic reactions that may be serious. If you experience swelling of the face, lips, throat or tongue, with or without difficulty breathing, stop taking Myrbetriq and tell your doctor right away.

Tell your doctor about all the medicines you take including medications for overactive bladder or other medicines such as thioridazine (Mellaril™ and Mellaril-S™), flecainide (Tambocor®), propafenone (Rythmol®), digoxin (Lanoxin®). Myrbetriq may affect the way other medicines work, and other medicines may affect how Myrbetriq works.

Before taking Myrbetriq, tell your doctor if you have liver or kidney problems. The most common side effects of Myrbetriq include increased blood pressure, common cold symptoms (nasopharyngitis), urinary tract infection, constipation, diarrhea, dizziness, and headache.

For further information, please talk to your healthcare professional and see accompanying Patient Product Information and complete Prescribing Information for Myrbetriq® (mirabegron).

Use and Dose of VESIcare
VESIcare is for OAB with symptoms of urgency, frequency and leakage. The

recommended dose of VESIcare is 5 mg once daily. If the 5 mg dose is well tolerated, your doctor may increase the dose to 10 mg once daily.

Important Safety Information for VESIcare
VESIcare is not for everyone. If you have certain stomach or glaucoma problems, or trouble emptying your bladder, do not take VESIcare. VESIcare may cause allergic reactions that may be serious. If you experience swelling of the face, lips, throat, or tongue, stop taking VESIcare and get emergency help. Tell your doctor right away if you have severe abdominal pain, or become constipated for three or more days. VESIcare may cause blurred vision, so use caution while driving or doing unsafe tasks. Common side effects are dry mouth, constipation, and indigestion.
For further information, please talk to your healthcare professional and see accompanying Patient Product Information and complete Prescribing Information for VESIcare® (solifenacin succinate).

You are encouraged to report negative side effects of prescription drugs to the FDA. Visit www.fda.gov/medwatch or call 1-800-FDA-1088.

References:
1. Abrams P, Cardozo L, Fall M, et al. The standardization of terminology of lower urinary tract function: report from the standardization sub-committee of the international continence society. Neurourology & Urodynamics. 2002; 21(2): 167–78.
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):1132-1138.
3. It's Time to Talk about OAB. Urology Care Foundation Web site. http://www.urologyhealth.org/OAB/patients.cfm. Accessed May 4, 2015.

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. We focus on Urology, Oncology, Immunology, Nephrology and Neuroscience as prioritized therapeutic areas while advancing new therapeutic areas and discovery research leveraging new technologies/modalities. We are also creating new value by combining internal capabilities and external expertise in the medical/healthcare business. Astellas is on the forefront of healthcare change to turn innovative science into value for patients. 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.

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