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News Release

For Immediate Release

Phase III results show mirabegron improves key OAB symptoms

- First presentations of European-Australian and North American Phase III trials at European Association of Urology Congress -

Tokyo, Japan, March 21, 2011: Astellas Pharma Inc.(TSE:4503,"Astellas") today announced the results of two pivotal phase III clinical trials for mirabegron, the first of a new class of compounds under development for the treatment of overactive bladder (OAB), show mirabegron significantly improves key OAB symptoms – urinary incontinence and frequency of micturition.[1,2] These data were presented for the first time this week at the 26th annual congress of the European Association of Urology, in Vienna, Austria, 18-22 March 2011.

After 12 weeks treatment with once daily mirabegron, significant improvements from baseline were seen in the co-primary endpoints, incontinence episodes/24 hours and micturitions/24 hours, compared with placebo ($p<0.05$)[1,2]. Significant improvements were also recorded in the key secondary endpoints – incontinence episodes/24 hours and micturitions/24 hours at week 4 of treatment ($p<0.05$ vs placebo), and volume of urine voided/micturition at the final visit ($p<0.05$ vs placebo)[1,2]. In both studies, mirabegron was well tolerated with low levels of adverse events[1,2].

"The findings of these studies are very exciting. Mirabegron would represent the first oral OAB drug treatment with a completely new mode of action since the launch of oxybutynin several decades ago, and, if approved, would represent the first beta-3 adrenoceptor agonist to ever come to the market. Unlike antimuscarinics, mirabegron works by improving the storage capacity of the bladder. As these two studies suggest mirabegron has the potential to provide an effective new treatment option for OAB patients who continue to suffer from the distressing symptoms of incontinence and frequent need to pass urine" said Mr. Vik Khullar, from St. Mary's Hospital, Imperial College, London, and principal investigator of the European-Australian Phase III trial.

Mirabegron is a potent and selective beta-3 adrenoceptor (β_3-AR) agonist which activates β_3-ARs on the detrusor muscle of the bladder to facilitate filling of the bladder and storage of urine[3,4]. It is being developed by Astellas whose global drug, Vesicare® (solifenacin) is currently one of the most widely used treatments for OAB[5].

"Vesicare has brought health benefits to people with OAB around the world since it was first launched in 2004, while mirabegron, with its different mode of action, complements Vesicare and is an important addition to our urology portfolio" said Masafumi Nogimori, President and Chief Executive Officer of Astellas Pharma Inc.

The new Phase III data confirm and support findings from smaller Phase II, dose-finding studies in which significant improvements were seen in a broad range of OAB symptoms, including incontinence episodes and micturition frequency[6,7].
"By improving symptoms through its action on beta-3 receptors, mirabegron offers an entirely different approach to existing OAB management which may provide good news for the many patients who are unable to achieve the right balance of efficacy and tolerability from current available treatments for OAB," said Dr. Victor Nitti, from NYU Langone Medical Center, New York, USA, and principal investigator of the North American Phase III trial.
Astellas submitted a market authorization application for mirabegron in Japan in June 2010 and expects the submission to FDA and EMA in 2Q fiscal year 2011(July to September, 2011).

About Astellas Pharma Inc.
Astellas Pharma Inc., located in Tokyo, Japan, is a global pharmaceutical company dedicated to improving the health of people around the world through the provision of innovative and reliable pharmaceutical products. Astellas has approximately 16,000 employees worldwide. The organization is committed to becoming a global category leader in urology, immunology and infectious diseases, neuroscience, DM complications and metabolic diseases and oncology. For more information on Astellas Pharma Inc., please visit our website at http://www.astellas.com/en.

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VESICARE

INDICATION AND DOSAGE

VESIcare tablets are indicated for the treatment of overactive bladder with symptoms of urge urinary incontinence, urgency, and urinary frequency. The recommended dose of VESIcare is 5 mg once daily. If the 5-mg dose is well tolerated, the dose may be increased to 10 mg once daily.

IMPORTANT SAFETY INFORMATION

VESIcare is contraindicated in patients with urinary retention, gastric retention, uncontrolled narrow-angle glaucoma, and in patients with hypersensitivity to the product.

Angioedema of the face, lips, tongue and/or larynx have been reported with VESIcare. In some cases angioedema occurred after the first dose. Angioedema associated with upper airway swelling may be life threatening. If involvement of the tongue, hypopharynx, or larynx occurs, VESIcare should be promptly discontinued and appropriate therapy and/or measures necessary to ensure a patent airway should be promptly provided.

VESIcare should be administered with caution to patients with bladder outflow obstruction, decreased gastrointestinal motility, controlled narrow-angle glaucoma, or reduced renal or hepatic function. Doses of VESIcare higher than 5 mg are not recommended in patients with severe renal impairment, moderate hepatic impairment, or when administered with ketoconazole or other potent CYP3A4 inhibitors. Use of VESIcare in patients with severe hepatic impairment is not recommended.

In placebo-controlled studies, the most common adverse events reported by patients were dry mouth (10.9%, 27.6%, 4.2%), constipation (5.4%, 13.4%, 2.9%), blurred vision (3.8%, 4.8%, 1.8%), and dyspepsia (1.4%, 3.9%, 1.0%) with VESIcare 5 mg, 10 mg, and placebo, respectively.

The overall rate of serious adverse events was 2%. For the 10-mg dose, three intestinal serious adverse events were reported (one fecal impaction, one colonic obstruction, and one intestinal obstruction). For the 5-mg dose, one case of angioneurotic edema was reported.