astellas
Leading Light for Life

News Release

July 1, 2009

# ASTELLAS ANNOUNCES SUBMISSION OF PEDIATRIC DATA FOR FLOMAX® CAPSULES IN THE US

**Tokyo, Japan, July 1, 2009 -** Astellas Pharma Inc. (headquarters: Tokyo; President and CEO: Masafumi Nogimori; "Astellas") today announced that Boehringer Ingelheim Pharmaceuticals, Inc. ("BIPI") submitted the data for FLOMAX® (generic name: tamsulosin hydrochloride, brand name in Japan: Harnal®) from a study involving pediatric patients with neurogenic bladder to the US Food and Drug Administration (FDA) on June 25, 2009.

Tamsulosin hydrochloride was invented and developed by Astellas for the treatment of the signs and symptoms of benign prostatic hyperplasia (BPH) and has been marketed in approximately 90 countries since it was launched in Japan in 1993. In the US, under a license from Astellas, BIPI has been marketing the product since 1997 under the brand name FLOMAX. Since October 2004, Astellas Pharma US, Inc., a US subsidiary of Astellas, has been co-promoting the product with BIPI.

The studies for FLOMAX in pediatric patients with neurogenic bladder were conducted in accordance with a pediatric Written Request issued by FDA in January 2006 with a deadline for the data submission on or before July 1, 2009. Pediatric exclusivity will be granted allowing an additional 6-months of market exclusivity for FLOMAX if FDA determines that the submitted study reports adequately respond to the Written Request. FDA normally makes this determination and notifies the sponsor within 90 days from the date the sponsor submits the study reports. The FLOMAX US substance patent expires in October 2009; however, if the data are officially accepted, the period of market exclusivity for Flomax will be extended to April 2010.

**Pediatric Study Findings**

The safety and efficacy of tamsulosin hydrochloride was not demonstrated in two studies conducted in pediatric patients 2 years to 16 years of age with elevated detrusor leak point pressure associated with known neurological disorder (e.g., spina bifida), referred to above as neurogenic bladder. Patients in both studies were treated on a weight-based mg/kg schema (0.025 mg, 0.05 mg, 0.1 mg, 0.2 mg, or 0.4 mg tamsulosin hydrochloride). In a randomized, double-blind, placebo-controlled, 14-week safety and efficacy study in 161 patients, no statistically significant difference in the proportion of responders was observed between groups receiving tamsulosin hydrochloride and placebo. In an open-label, 12-month safety study, 87 patients were treated with tamsulosin hydrochloride. The most frequently reported adverse events (≥5%) from the pooled data of both studies were urinary tract infection, vomiting, pyrexia, headache, nasopharyngitis, cough, pharyngitis, influenza, diarrhea, abdominal pain, and constipation.

**Important Safety Information about FLOMAX**

FLOMAX is approved to treat male urinary symptoms due to BPH, also called an enlarged prostate. Only your doctor can tell if you have BPH, not a more serious condition like prostate cancer. Avoid driving or hazardous tasks for 12 hours after your first dose or increase in dose, as a sudden drop in blood pressure may occur, rarely resulting in fainting. If considering cataract surgery, tell your eye surgeon you've taken FLOMAX. Common side effects are runny nose, dizziness and decrease in semen.

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.

Before taking FLOMAX capsules, please see the full Prescribing Information and Patient Information, available at www.4FLOMAX.com.

########


| Contacts for inquiries or additional information |
| --- |
| Astellas Pharma Inc.<br>Corporate Communications<br>Tel: +81-3-3244-3201 Fax: +81-3-5201-7473<br>http://www.astellas.com |