astellas
Leading Light for Life

News Release

August 11, 2009

# Astellas Announces the Outcome of its Citizen Petition in the US

**Tokyo, Japan, August 11, 2009**- Astellas Pharma Inc. ("Astellas"; headquarters: Tokyo; President and CEO: Masafumi Nogimori) announced today that its North American affiliate, Astellas Pharma US, Inc. received notice that the U.S. Food and Drug Administration (FDA) has substantially denied the company's Citizen Petition*[1], which had been submitted in September 2007, to ensure the safe and effective use of oral immunosuppressants used in organ transplant patients on August 10, 2009 (local time). In response, Astellas Pharma US plans to file a complaint in U.S. District Court in Washington, D.C. challenging the FDA's decision.

The purpose of this petition is to ensure the safe and effective use of orally administered immunosuppressant used in transplant patients and characterized by a narrow therapeutic index (NTI). In this petition, Astellas requested that bioequivalence clinical trials in transplant patients*[2] be required for approval of substitute critical dose immunosuppressants. Additionally, Astellas will request labeling changes that require prescribing physicians to be notified if substitution of another oral immunosuppressant is contemplated by the pharmacist.

Astellas believes that the additional measures are necessary to ensure the safe and effective treatment in transplant recipients. Astellas Pharma US plans to file a complaint in U.S. District Court in Washington, D.C. challenging the FDA's decision. Additionally, Astellas Pharma US will request the court to issue a preliminary injunction enjoining the FDA's approval of abbreviated new drug application(s) (ANDA(s)) for tacrolimus to ensure the safe and effective treatment in transplant recipients considering the fact that the validity of FDA's decision is being disputed in the court.

*[1]About Citizen Petition
A Citizen Petition is a formal request asking FDA to issue, change or cancel a regulation, or to take other action under the laws administered by the agency. FDA receives about 200 petitions yearly.

*[2]About bioequivalence clinical trials in transplant patients
Bioequivalence testing measures how closely the absorption of the active ingredient in a substitution drug mirrors that of an innovator drug. A substitution must demonstrate that it falls within an acceptable range of absorption, as compared to the innovator drug. Absorption, and the clinical effect of these critical dose drugs, is affected by a number of factors, including interactions with other medications, and concurrent medical conditions. Transplant patients are at high risk for organ rejection and are often dealing with a host of medical issues, as well as taking an average of ten medications including oral immunosuppressants characterized by Narrow Therapeutic Index. Under FDA's decision, bioequivalence testing is required only in healthy volunteers.

#####

| 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 |