astellas
Leading Light for Life

News Release

For Immediate Release

Contacts: Maribeth Landwehr
Astellas US LLC
(847) 317-8988

Sarah Vura
Fleishman-Hillard
(216) 928-3452

ASTELLAS RECEIVES FDA APPROVAL OF PROGRAF® (TACROLIMUS) FOR USE IN HEART TRANSPLANT RECIPIENTS

Heart indication for Prograf reinforces a 20-year commitment to research and development in transplantation

DEERFIELD, IL, MARCH 31, 2006 – The Food and Drug Administration (FDA) has granted Astellas Pharma US, Inc. approval for the use of Prograf as an immunosuppressant to prevent organ rejection in patients who have received a heart transplant. This is the third organ transplant indication in which Prograf has received FDA approval; Prograf is currently used as cornerstone therapy to treat the majority of patients undergoing kidney and liver transplants. The additional indication for use in heart transplant recipients is a milestone for Astellas and coincides with the one year anniversary of its formation following the 2005 merger between Fujisawa Pharmaceutical Co., Ltd. and Yamanouchi Pharmaceutical Co., Ltd.

The FDA's review of Prograf for use in heart transplant patients was based on two open-label, randomized, comparative clinical studies—one U.S-based study, and one European-based study. The studies represented a total of 645 heart transplant recipients and evaluated the safety and efficacy of Prograf-based vs. cyclosporine-based immunosuppression in primary orthotopic heart transplantation.

"With only a few thousand heart transplants occurring annually, very few randomized clinical trials have been conducted in heart transplant recipients," said Dr. Jon Kobashigawa, principal investigator for the U.S.-based clinical study, and medical director of the UCLA Heart Transplant Program. "The results of these studies, and the subsequent FDA approval, provide important data that can be applied to benefit heart transplant recipients."

(more)

"The approval of Prograf for use in heart transplant patients represents a major milestone for both Astellas and the transplant community," said M. Roy First, M.D., Vice President, Medical Affairs for Astellas Pharma US, Inc. "This FDA approval also provides evidence of our ongoing commitment to research and development in the field of immunology and transplantation."

Clinical Studies for Use of Prograf in Heart Transplantation

Two open-label, randomized, comparative studies evaluated the safety and efficacy of Prograf-based and cyclosporine-based immunosuppression in primary orthotopic heart transplantation. In a Phase 3 study conducted in Europe, 314 patients received a regimen of antibody induction, corticosteroids and azathioprine in combination with Prograf or cyclosporine modified for 18 months. In a 3-arm study conducted in the U.S., 331 patients received corticosteroids and Prograf plus sirolimus, Prograf plus mycophenolate mofetil (MMF) or cyclosporine modified plus MMF for 1 year.

In the European Phase 3 study, patient/graft survival at 18 months post-transplant was similar between treatment arms, 91.7% in the tacrolimus group and 89.2% in the cyclosporine group. In the U.S. study, patient and graft survival at 12 months was similar with 93.5% survival in the Prograf plus MMF group and 86.1% survival in the cyclosporine modified plus MMF group.

About Prograf® (tacrolimus)

Prograf® is indicated for the prophylaxis of organ rejection in patients receiving a kidney, liver or heart transplant in the U.S. and has been marketed in North America, Europe and Japan. Worldwide, Prograf® is commercially available in approximately 70 countries.

Increased susceptibility to infection and the possible development of lymphoma may result from immunosuppression. Only physicians experienced in immunosuppressive therapy and management of organ transplant patients should prescribe Prograf®. Insulin dependent post-transplant diabetes mellitus was reported in 13% and 22% of Prograf-treated heart transplant patients in the U.S. and European studies, respectively, but was reversible in some patients. Black and Hispanic kidney transplant patients were at an increased risk for post-transplant diabetes mellitus. The more common adverse reactions in Prograf-treated heart transplant recipients were abnormal renal function, hypertension, diabetes mellitus, CMV infection, tremor, hyperglycemia, leukopenia, infection, and hyperlipemia.

Prograf® is contraindicated in patients with a hypersensitivity to tacrolimus. Prograf® injection is contraindicated in patients with a hypersensitivity to castor oil. The safety and efficacy of the use of tacrolimus with sirolimus has not been established. For full prescribing information, visit www.prograf.com or contact Astellas at 1-800-727-7003.

(more)

astellas
Leading Light for Life

News Release

About Astellas
Astellas Pharma US, Inc. is a subsidiary of Astellas Pharma Inc., located in Tokyo, a pharmaceutical company dedicated to improving the health of people around the world through the provision of innovative and reliable pharmaceutical products. In April 2005, the company was formed through the merger of Fujisawa Pharmaceutical Co., Ltd. and Yamanouchi Pharmaceutical Co., Ltd. The organization is committed to becoming a global mega pharmaceutical company by combining outstanding R&D and marketing capabilities and continuing to grow in the world pharmaceutical market. **For free educational information related to transplantation visit www.transplantexperience.com**

# # #

MEDIA NOTE – The following are available for interview regarding this FDA approval:

- M. Roy First, M.D., Vice President, Medical Affairs, Astellas Pharma US, Inc.: www.transplantexperience.com
- Jon Kobashigawa, M.D., Medical Director of the UCLA Heart Transplant Program: http://www2.healthcare.ucla.edu/transplant/default.htm
  (*Disclosure Note: Dr. Kobashigawa receives research grants and speaker honoraria from Astellas and is a member of the company's scientific advisory board.*