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Astellas Announces Acceptance of U.S. New Drug Application for Tacrolimus Extended Release Capsules

NORTHBROOK, IL. Dec., 4, 2012 – Astellas Pharma US, Inc. (“Astellas”), a U.S. subsidiary of Tokyo-based Astellas Pharma Inc. (Tokyo: 4503), announced today that the U.S. Food and Drug Administration (FDA) has accepted for review the company’s New Drug Application (NDA) for tacrolimus extended release capsules, for the prophylaxis of organ rejection in adult kidney transplant recipients and adult male liver transplant recipients. Based upon the September receipt of the NDA submission, the FDA Prescription Drug User Fee Act (PDUFA) review date will be July 21, 2013.

"The NDA acceptance for tacrolimus extended release capsules marks an important step toward addressing the unmet treatment need for transplant recipients who have difficulty controlling their immunosuppression drug levels with existing products," said Roy First, MD, Astellas Global Therapeutic Area Head for Transplantation. "Astellas has been committed to the field of immunology for more than 20 years and plans to continue that commitment by working to bring promising new treatments for patients to market."

Developed by Astellas, tacrolimus extended release capsules are a once daily formulation of the calcineurin-inhibitor immunosuppressant tacrolimus. The NDA submission is based on six randomized and comparative studies of 2,842 (1,689 tacrolimus extended release) kidney transplant recipients and 689 (393 tacrolimus extended release) liver transplant recipients conducted in the U.S., Canada, Europe, Australia, Brazil, New Zealand, among other sites. Astellas also has more than five years of follow-up patient data from the treatment of transplant recipients with tacrolimus extended release capsules.

Astellas was granted marketing approval for tacrolimus extended release capsules under the trade name Advagraf® in Europe in 2007 and under the trade name Graceptor® in Japan in 2008. In total, tacrolimus extended release capsules have been approved for use in 69 countries resulting in more than 140,000 patient years of experience.

About Astellas

Astellas Pharma US, Inc., located in Northbrook, Illinois, is a US affiliate of Tokyo-based Astellas Pharma Inc. Astellas is a pharmaceutical company dedicated to improving the health of people around the world through the provision of innovative and reliable pharmaceutical products. The organization is committed to becoming a global category leader in focused areas by combining outstanding R&D and marketing capabilities. For more information about Astellas Pharma US, Inc., please visit our website at www.Astellas.us or www.AstellasTransplant.com.

Astellas is a recognized leader in transplantation and has been committed to the field of immunology for more than 20 years. Dedicated to supporting the advancement of care for patients, Astellas continues to build upon its legacy and leadership in transplantation by investing in ongoing clinical research and new product development.

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