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FDA accepts Astellas' NDA for organ rejection drug

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Singapore: Astellas Pharma, US, a US subsidiary of Tokyo-based Astellas Pharma, received US FDA acceptance for review of 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 Mr 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 US, 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.