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News Release

March 20, 2007

Astellas Receives an FDA Action Letter for Prograf sNDA

Japan, March 20, 2007 - Astellas Pharma Inc. (headquarters: Tokyo, president and CEO: Masafumi Nogimori) today announced that its US subsidiary, Astellas Pharma US, Inc. (headquarters: Deerfield, IL) received an action letter from the U.S. Food and Drug Administration (FDA) for the Supplemental New Drug Application (sNDA) for the use of the immunosuppressant Prograf® (generic name: tacrolimus) plus mycophenolate mofetil (MMF) as an adjunct therapy for the prophylaxis of organ rejection in kidney transplant patients on March 15, 2007 (local time). Prograf is currently approved for the prevention of rejection in kidney, liver and heart transplant recipients in the US.

While the action letter was approvable, the FDA raised concerns that the combination of Prograf with MMF starting dose (2g/day) may lead to an increase in infection-related mortality related to over-immunosuppression based on their review of a clinical study in the sNDA. The submitted study, recently published in the March 2007 issue of the *American Journal of Transplantation*, was a three-arm, multicenter, phase III, randomized, open-label study involving 638 kidney transplant recipients. The one year patient survival rate in the three study arms was 95.7% in the Prograf/MMF, 97.6% in the cyclosporine modified/MMF and 98.6% in the extended release tacrolimus (FK506 Modified Release)/MMF.

The peer-reviewed literature and the United Network for Organ Sharing (UNOS) database do not show significant differences in survival rates among patients receiving the combination of MMF with Prograf or cyclosporine modified. Astellas plans to work with the FDA to resolve the differences in interpretation of the data and pursue approval of this sNDA.

Tacrolimus is an immunosuppressant discovered by Astellas. Prograf has been marketed in approximately 70 countries around the world. Prograf was launched in the United States in 1994 with the indication of prophylaxis for organ rejection in liver transplant recipients, and received approval for the prophylaxis for organ rejection in kidney transplant recipients in 1997 and in heart transplant recipients in 2006. Prograf has been established as a cornerstone therapy for prophylaxis for organ rejection in kidney, liver, and heart transplant recipients

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