

News Release

For Immediate Release

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STUDY DEMONSTRATES IMPROVED RENAL FUNCTION AND LIPID VALUES IN KIDNEY TRANSPLANT PATIENTS ON PROGRAF[®] COMPARED TO PATIENTS TAKING NEORAL[®]

Two Follow-Up Studies Indicate Better Renal Function for Patients with Chronic Graft Dysfunction Converted to Prograf[®]

BOSTON, July 25, 2006 – Research presented today at the World Transplant Congress (WTC) revealed that after only six months post-conversion from Neoral[®] (cyclosporine or CsA) to Prograf[®] (tacrolimus or TAC), stable kidney transplant recipients experienced improved renal function and lipid values compared to those who remained on Neoral. Improved lipid values potentially indicate better long-term cardiac health. The study analyzed three groups of patients after conversion and compared those who remained on Neoral with two groups converted to Prograf (target trough levels; 3.0-5.9 ng/mL and 6.0-8.9 ng/mL respectively). Renal function was assessed through serum creatinine, cystatin C and Cockcroft-Gault estimate of creatinine clearance.

In another study presented today, five year follow-up results indicated that conversion from Neoral to Prograf resulted in significantly better renal function and fewer cardiac complications in kidney transplant recipients with chronic graft dysfunction compared to those who remained on Neoral. Renal function parameters assessed included serum creatinine, estimated creatinine clearance and blood urea nitrogen (BUN). The study found that patient and graft survival, acute rejection rates and incidence of new onset diabetes mellitus (NODM), were similar in Neoral and Prograf patients.

"Cardiovascular disease is a leading cause of death in long-term transplant survivors. Chronic allograft nephropathy is also an important cause of late graft loss," said Fuad S. Shihab, Professor of Medicine and Medical Director of Kidney Transplantation at the University of Utah and also a lead investigator of both studies. "It is important for us to continue to work on

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identifying factors that can improve cardiovascular risks and long-term renal function so that more transplant recipients can maintain healthy grafts and lead longer, healthier lives."

Optimizing Tacrolimus Therapy in Maintenance Renal Allografts: Six Month Results

A prospective, randomized, multi-center study comparing cyclosporine (CsA) to two different whole blood trough level ranges of tacrolimus (TAC) to evaluate renal function, optimal dose/blood level of TAC and changes in cardiovascular risk factors. The open-label study of 323 patients, six months or more post-transplant on a CsA-based regimen, were randomized to remain on CsA (n=111), convert to TAC with trough levels 3.0-5.9 ng/mL (n=100) or 6.0-8.9 ng/mL (n=112). There was no difference in demographics, patient and graft survival, or biopsy-proven acute rejection among treatment groups.

Renal function assessed by serum creatinine, cystatin C and Cockcroft-Gault estimate of creatinine clearance were similar at six months; however, change from baseline for all three parameters was significantly greater in the TAC groups – serum creatinine (-0.10 in TAC groups compared to 0.00 in CsA group); cystatin C (-0.10, -0.04 in TAC groups compared to 0.07 in CsA group); Cockcroft-Gault (3.30, 0.00 in TAC groups compared to -0.65 in CsA groups). All lipid values (total cholesterol, LDL, triglycerides) were significantly lower in both TAC groups six months after conversion.

Tacrolimus as Secondary Intervention vs. Cyclosporine in Patients at Risk for Chronic Renal Allograft Failure: Five Year Results

A prospective, randomized, open-label study conducted to assess the progression of chronic renal allograft dysfunction in cyclosporine (CsA) treated patients randomized in a two-to-one fashion to convert to tacrolimus (TAC) or remain on CsA. The multi-center study involved 186 patients receiving CsA with an elevated serum creatinine (SCr) at least three months post renal transplantation were randomized and had follow-up. Elevated SCr was defined as ≥ 2.0 mg/dL for males and as ≥ 1.7 mg/dL for females, or a $>30\%$ rise over post-transplant nadir. Sixty patients remained on CsA and 126 patients were converted to TAC. There were no significant demographic differences between groups. Protocol biopsies were performed at baseline (BL) and Month 60.

In renal transplant patients with chronic allograft dysfunction, 60 month follow-up indicated that conversion from CsA to TAC resulted in significantly better renal function (9.3% SCr > 3.0 mg/dL in TAC group compared to 36.8% SCr > 3.0 mg/dL in CsA group) and change in renal function from baseline compared to patients maintained on CsA (-0.2 in TAC group compared to +0.3 in CsA group). In addition there were significantly fewer new cardiac conditions following conversion to TAC (9.0% in TAC group compared to 33.3% in CsA group), while patient and graft survival, acute rejection rates and incidence of new onset diabetes mellitus were comparable between the groups.

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About Prograf® (tacrolimus)

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

Only physicians experienced in immunosuppressive therapy and management of organ transplant patients should prescribe Prograf. Increased susceptibility to infection and the possible development of lymphoma may result from immunosuppression. Insulin-dependent post-transplant diabetes mellitus was reported in 11% to 22% of Prograf-treated liver, kidney, and heart transplant patients with no prior history of diabetes mellitus, but was reversible in some patients. Black and Hispanic kidney transplant patients were at increased risk. Prograf has been associated with nephrotoxicity, particularly when used in high doses. Common adverse reactions include tremor, headache, hypertension, gastrointestinal disturbance, abnormal renal function, hyperglycemia, leukopenia, CMV infection, 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. For full prescribing information please visit www.prograf.com or call Astellas at 1-800-727-7003.

About Astellas

Astellas Pharma US, Inc., located in Deerfield, 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 pharmaceutical company by combining outstanding R&D and marketing capabilities and continuing to grow in the world pharmaceutical market. For more information about Astellas Pharma US, Inc., please visit our website at www.astellas.com/us. **For free educational information related to transplantation visit www.transplantexperience.com**

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