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**LIVING DONOR KIDNEY TRANSPLANTS USING ALEMTUZUMAB PRE-CONDITIONING
AND TACROLIMUS MONOTHERAPY: LONG-TERM SAFETY AND EFFICACY**

*The results of these studies will be presented during the
American Transplant Congress in Boston, MA May 30 – June 3, 2009*

Columbia, MD, May 31, 2009 –The results of two large studies presented by researchers from the Starzl Transplant Institute at the University of Pittsburgh Medical Center demonstrated the long-term safety and efficacy of alemtuzumab induction and tacrolimus monotherapy.

Led by Dr. Henkie Tan, this group performed 200 consecutive living donor kidney transplants using a regimen of alemtuzumab pre-conditioning and tacrolimus monotherapy with subsequent weaning. Beginning at 6 months posttransplant and at 2-6 month intervals, they used a battery of clinical data including ELISA antibody titers, donor-specific antibodies and the ImmuKnow® assay to wean tacrolimus whenever possible. Patients were followed in this manner for an average of 50.0 (± 11.6) months.

Actuarial recipient survival after 1, 2, 3, 4, and 5 years were 99.0%, 96.5%, 94.4%, 92.0% and 87.1%, respectively. Graft survivals at the same time points were 98.0%, 90.5%, 87.5%, 80.1%, and 73.7%, respectively. The mean (\pm SD) creatinine (mg/dL) after 1, 2, 3, and 4 years were 1.43 (± 0.55), 1.58 (± 1.13), 1.51 (± 0.89), and 1.55 (± 1.46), respectively. The mean (\pm SD) GFR (mL/min/1.73m²) at these time points were 58.7 (± 21.6), 55.1 (± 21.4), 55.3 (± 21.1), and 57.6 (± 24.6), respectively. The cumulative incidence of acute cellular rejection (ACR) at 1, 3, 6, 12, 18, 24, 30, 36, 42, and 48 months were 1.0%, 1.0%, 2.0%, 9.0%, 16.5%, 19.5%, 24.0%, 24.5%, 28.0%, and 28.5%, respectively. Most recipients (77.0%) were weaned to every-other-day or less dosing of tacrolimus monotherapy. Among 60 recipients with ACR, the incidence of pre-weaning ACR was 8.5% and post-weaning ACR was 27.9%. At this time, $\geq 90\%$ of recipients remain steroid-free on tacrolimus monotherapy.

In a similar study report, Dr. Tan and colleagues performed 478 consecutive unselected living donor kidney transplants using alemtuzumab pre-conditioning and tacrolimus monotherapy. Once again, they used a series of clinical tests including ELISA antibody titers, donor-specific antibodies and the ImmuKnow assay beginning 6 months posttransplant and at 2-6 months intervals. Using these data, tacrolimus was weaned whenever possible. These patients were followed for an average of 35.6 (± 19.7) months.

Recipient survivals at 1, 2, 3, and 4 years were 98.4%, 95.3%, 93.3%, and 90.4%, respectively. Graft survivals at the same time points were 97.1%, 89.6%, 85.2%, and 77.5%, respectively. The mean (\pm SD)



creatinine (mg/dL) after 1, 2 and 3 years were 1.42 (± 0.61), 1.56 (± 0.96) and 1.53 (± 0.83), respectively. The mean (\pm SD) GFR (mL/min/1.73m²) at these time points were 59.2 (± 23.6), 55.0 (± 21.7) and 53.9 (± 21.7), respectively. The cumulative incidence of ACR after 1, 3, 6, 12, 18, 24, 30, and 36 months were 1.9%, 3.1%, 4.2%, 9.2%, 14.0%, 16.3%, 18.8% and 19.5%, respectively.

Weaning to every-other-day or less dosing of tacrolimus monotherapy was attempted in 41% of patients. Among 397 patients with functional grafts, 82 (20.6%) are on spaced-dose tacrolimus monotherapy. A total of 114 recipients had ACR. The incidence of pre-weaning ACR was 11.7% and post-weaning was 30.1%. At this time, $\geq 80.6\%$ of recipients remain steroid-free on tacrolimus monotherapy.

The use of the ImmuKnow assay as described in these studies has not been cleared by the U.S. Food & Drug Administration.

About ImmuKnow

ImmuKnow is a noninvasive biomarker of immune function that assesses cellular immune status by detecting cell-mediated immunity (CMI) in adult immunosuppressed patients. It measures the concentration of adenosine triphosphate (ATP) released from CD4 cells following cell stimulation. The ImmuKnow test is a qualitative assay and does not directly quantify the level of immunosuppression. Results of the ImmuKnow assay should be used in conjunction with clinical presentation, medical history, and other clinical indicators when assessing the immune status of any individual patient.

About Cylex, Inc.

Cylex is a privately held global life sciences company that is the leader in the development and manufacture of *in vitro* diagnostic products that are intended to illuminate immunity. ImmuKnow is the *in vitro* diagnostic utilized to detect cell-mediated immunity (CMI) in an immunosuppressed population, and is increasingly being adopted at organ transplant centers throughout the United States and abroad. The Company's patented technology provides an innovative platform allowing clinicians to simply and reproducibly assess CMI. The Company is based in Columbia, MD USA.