Active Clinical Trials

1. **Genentech Efalizumab**
   Protocol No. ACD4230g
   PI: Dr. Sander Florman
   Title: A Phase II/III, Randomized, Open-Label, Active-Controlled, Multicenter Trial to Evaluate the Safety and Efficacy of Efalizumab compared with Cyclosporine, both in combination with Mycophenolate Mofetil and Corticosteroids as an Immunosuppressant regimen in de novo renal transplantation
   Contact: Brandy Haydel at 504-988-8260
   Susan Staulcup at 504-988-3312
   Status: Enrollment expected to open September 2008

   The purpose of this study is to evaluate the safety and efficacy of efalizumab compared to cyclosporine, when both are given in combination with mycophenolate mofetil (MMF) and corticosteroids, on patient and graft survival and transplant renal function, in patients undergoing their first renal transplantation. Patients will be randomly assigned to receive either Cyclosporine or weekly injections of Efalizumab. All patients will be followed for one year.

2. **Chimerix, Inc**
   Protocol No. CMX001-104
   PI: Dr. Sander Florman
   Title: A Multicenter, randomized, double-blind, placebo-controlled, multiple dose study of the safety, tolerability and population pharmacokinetics of CMX001 in post-transplant subjects with BK virus viruria.
   Contact: Brandy Haydel at 504-988-8260
   Susan Staulcup at 504-988-3312
   Status: Enrollment expected to open October 2008

3. **ZymoGenetics Inc. APRIL LN**
   Protocol No. 493G01
   PI: Dr. Myra Kleinpeter
   Title: A Phase 2/3, Randomized, Double-Blind, Placebo-Controlled Study to Evaluate the Safety and Efficacy of Atacicept in Subjects with Class III or IV Lupus Nephritis in Combination with Mycophenolate Mofetil Therapy
   Contact: Brandy Haydel at 504-988-8260
   Susan Staulcup at 504-988-3312
   Status: Enrollment expected to open August 2008

The purpose of this study is to evaluate the safety and efficacy of atacicept compared to placebo in subjects with active lupus nephritis (LN) receiving immunosuppressive therapy with mycophenolate mofetil (MMF). Patients with active LN who qualify will be

randomized to receive either atacicept or placebo. Atacicept (150 mg) or placebo will be administered subcutaneously (SC) twice per week for 4 weeks (loading period) followed by once-weekly administration thereafter for 48 weeks (maintenance period), for a total treatment duration maximum of 52 weeks.

4. **Roche Tamiflu Treatment**
   Protocol No. NV20234
   PI: Dr. Brent Alper
   Title: A double-blind, randomized, stratified, multi-center trial evaluating conventional and high dose oseltamivir in the treatment of immunocompromised patients with influenza
   Contact: Brandy Haydel at 504-988-8260
   Susan Staulcup at 504-988-3312
   Status: Enrollment Closed

   The purpose of this study is to see how well Oseltamivir (Tamiflu) works in treating transplant patients with influenza. A total of approximately 250 patients (adults and children) will be enrolled in this study and receive study drug (oseltamivir only or oseltamivir and placebo) in either the currently approved (conventional) dose or the high dose (2X the conventional dose) twice daily for a period of 10 days for the treatment of flu. The total length of participation in this study is 40 days. During the first 10 days patients will be required to take the study drug. Fifteen and thirty days after the last dose they will be required to come back to the hospital/office for a follow up visit.

5. **ArtisanPharma, Inc. Sepsis**
   Protocol No. 2-0001
   PI: Dr. Juan Duchesne
   Title: A Randomized, Double-Blind, Placebo-Controlled, Phase 2b Study to Assess the Safety and Efficacy Effects of ART-123 on Subjects with Sepsis and Disseminated Intravascular Coagulation
   Contact: Brandy Haydel at 504-988-8260
   Susan Staulcup at 504-988-3312
   Status: Enrollment Open

   The purpose of this study is to evaluate the efficacy of an experimental drug ART-123 (a soluble recombinant human thrombomodulin) on subjects with sepsis and disseminated intravascular coagulation. Patients who meet eligibility criteria will be randomized to receive either placebo or ART-123. Medication will be administered for a total of 6 days. Patients are required to complete a follow-up visit 28 days following the first dose of medication.

6. **Therapeutic Monitoring Services, INC.**
   PI: Dr. Sander Florman
   Title: Comparison of High Performance Liquid Chromatography – Tandem Mass Spectrometry to current analytic methods utilized in therapeutic drug Monitoring of immunosuppressants in organ transplantation patients to assess Method performance and the potential for low volume sampling of blood.
   Contact: Brandy Haydel at 504-988-8260
   Susan Staulcup at 504-988-3312
   Status: Enrollment Open

The purpose of this study is to compare the accuracy of (LC-MS/MS) analysis to the current analytic methods used in therapeutic drug monitoring of immunosuppressants in abdominal organ transplant patients. It has been proposed that the ability of the (LC – MS/MS)system to analyze small volumes of blood could be adapted to provide a process where patients could obtain their blood sample at home by finger stick and mail the sample to a lab for testing, thereby establishing a system for improved compliance and accuracy. If proven accurate, the LC-MS/MS system could become a routine practice which could lead to increased compliance, improved sampling at correct post-dose intervals, and more accurate drug level analysis results. Patients are required to visit the clinc for a total of 10 visits to monitor drug levels by finger-stick.

7. **BMS Belatacept Conversion**
   Protocol No. IM103-010
   PI: Dr. Sander Florman
   Title: Belatacept Conversion Study in Renal Transplantation
   Contact: Brandy Haydel at 504-988-8260
   Susan Staulcup at 504-988-3312
   Status: Enrollment Closed

   The purpose of this study is to convert renal transplant patients from a calcineurin inhibitor (CNI)-based immunosuppression regimen to a belatacept-based regimen in order to preserve renal function. Patients will be randomized to either continue their current therapeutic regimen or to receive belatacept with a tapered discontinuation of the CNI. The duration of the study is one year.

8. **Astellas MR Tacrolimus (Fujisawa)**
   Protocol No. 02-0-158 (S0516)
   PI: Dr. Douglas Slakey
   Title: A Phase III, Randomized, Open-Label, Comparative, Multi-Center Study to Assess the Safety and Efficacy of Prograf (Tacrolimus) / MMF, Modified Release (MR) Tacrolimus / MMF and Neoral (Cyclosporine) / MMF in De Novo Kidney Transplant Recipients
   Contact: Brandy Haydel at 504-988-8260
   Susan Staulcup at 504-988-3312
   Status: Enrollment Closed, patients in follow-up

The purpose of this study is to evaluate the safety and efficacy of the study drug, modified release (MR) tacrolimus/MMF therapy compared to the Prograf® /MMF or Neoral/MMF therapy in preserving kidney function and preventing rejection in patients receiving their first kidney transplant. MR tacrolimus and Prograf® contain the same active drug. However, it is delivered to the body differently in each formulation. As a result, MR tacrolimus can only be taken once a day, whereas Prograf® and Neoral are given twice a day.

9. **Roche Spare the Nephrons**
   Protocol Number: ML17140/01265 (S0505)
   PI: Dr. Douglas Slakey
   Title: An Open-Label Randomized, Multi-Center Study to Evaluate the Efficacy and Safety of Early Calcineurin Inhibitor Withdrawal in Recipients of Primary Renal Allografts Maintained Long-Term on Mycophenolate Mofetil: MMF (Cellcept) and Sirolimus (Rapamune)
   Contact: Brandy Haydel at 504-988-8260
   Susan Staulcup at 504-988-3312
   Status: Enrollment closed, data under analysis

The purpose of this study is to test a new treatment regimen combining CellCept and sirolimus in the absence of calcineurin inhibitor to determine if long-term renal function is preserved and long-term outcomes are improved. Patients are randomized (as in the flip of a coin) to one of the two main treatment groups, either the Calcineurin Inhibitor Withdrawal Group (Study Arm), or the Calcineurin Inhibitor Maintenance Group (Control Arm).

10. **BMS Belatacept**
   Protocol Number: IM103027 (F0216)
   PI: Dr. Sander Florman
   Title: Belatacept Evaluation of Nephroprotection and Efficacy as First-Line Immunosuppression Trial – Extended Criteria Donors (BENEFIT-EXT)
   Contact: Brandy Haydel at 504-988-8260
   Susan Staulcup at 504-988-3312
   Status: Enrollment closed, patients in follow-up

The purpose of this study is to evaluate the effects of the study drug, belatacept compared to Cyclosporine on subject and kidney transplant survival and the preservation of glomerular filtration rate (GFR). This study includes patients who will receive a donor organ that meets extended donor criteria. These extended criteria donors are older donors or donors who have had some risk factors. Patients will be randomized to either belatacept or cyclosporine. Randomization is partially blinded. Patients will know whether they are receiving cyclosporine or belatacept; however the specific intensity of belatacept dosing will remain unknown. These patients will be followed for 3 years.

11. **Novartis Certican**

Protocol Number: CRAD001A2309

PI: Dr. Slakey

Title: A 24-Month, Multicenter, Randomized, Open-Label Non-Inferiority Study of Efficacy and Safety Comparing Concentration-Controlled Certican® in two doses (1.5 and 3.0mg/day starting doses) with reduced Neoral in de novo renal transplant recipients

Contact: Brandy Haydel at 504-988-8260
Susan Staulcup at 504-988-3312

Status: Enrollment closed, patients in follow-up

The purpose of this study is to compare the composite efficacy failure rate (treated biopsy proven acute rejection, graft loss, death, and loss to follow-up) between de novo transplant patients treated with Certican and reduced Neoral dose and Myfortic with standard Neoral dose at 12 months.

12. **Isotechnika**

Protocol: ISA05-01

PI: Dr. Rubin Zhang

Title: A Phase IIB, Randomized, Multicenter, Open-Label, Concentration Controlled, Safety Study of ISA247 and Tacrolimus (Prograf®) in *De Novo* Renal Transplant Patients.

Contact: Brandy Haydel at 504-988-8260
Susan Staulcup at 504-988-3312

Status: Enrollment closed, patients in follow-up

The purpose of this study is to evaluate whether or not ISA247 is safe and effective in preventing rejection of the transplanted kidney. This study medication will be compared to tacrolimus which is one of the immunosuppressant medications typically used to prevent rejection in patients who have just received a kidney transplant.

13**. Novartis Certican Umbrella**

Protocol No. RAD001A2410

PI: Dr. Douglas Slakey

Title: A facilitated access program to provide Everolimus (RAD) for maintenance patients completing therapy in RAD trials in solid organ transplantation

The purpose of this study is to continue use of Certican in Kidney transplant patients who have successfully completed the Novartis RAD001A2309 protocol. Patients will be seen every 6 months and will be provided with Certican until available on the market.