Liver Transplant Clinical Trials

1. **BMS Baraclude**
   Protocol Number: AIG163-109
   PI: Dr. Sander Florman
   Title: A Study of the Antiviral Activity of Entecavir in Patients Receiving Liver Transplant Due to Chronic Hepatitis B Infection
   Contact: Brandy Haydel at 504-988-8260
   Susan Staulcup at 504-988-3312
   Status: Enrollment expected to open August 2008

2. **BMS Belatacept Liver**
   Protocol Number: IM103-045
   PI: Dr. Sander Florman
   Title: Evaluation of Belatacept as First Line Immunosuppression in De Novo Liver Transplant Recipients
   Contact: Brandy Haydel at 504-988-8260
   Susan Staulcup at 504-988-3312
   Status: Enrollment open

3. **Viropharma, Inc. Maribavir**
   Protocol Number: 1263-301
   PI: Dr. Mary Killackey
   Title: A Randomized Double Blind Study to Assess the Eficacy and Safety of Prophylactic Use of Maribavir versus Oral Ganciclovir for the Prevention of Cytomegalovirus Disease in Recipients of Othotopic Liver Transplant
   Contact: Brandy Haydel at 504-988-8260
   Susan Staulcup at 504-988-3312
   Status: Enrollment Open

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 Open

   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. **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.

6. **Astellas Pediatric MR Tacrolimus (Fujisawa)**
   Protocol Number: 03-0-160 (F0196)
   PI: Dr. Sander Florman
   Title: A Phase II, Multi-Center, Open-Label, Study to Assess the Pharmacokinetics, Long-Term Safety and Efficacy and Tolerability of Tacrolimus in Stable Pediatric Liver Transplant Patients Converted from a Prograf Based Immunosuppression Regimen
   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 assess the long-term safety and tolerability, of modified release (MR) Prograf® compared to the Prograf® immunosuppression regimen in stable pediatric liver transplant patients. Prograf ® (tacrolimus) is currently taken two times a day. Both treatments in this study contain a new formulation of tacrolimus (generic name for Prograf®), and as a result, patients participating will take MR tacrolimus once every day. The study period is a total of 2 weeks for the pharmacokinetic (PK) followed by a two year extension period. (The term “pharmacokinetic” refers to measuring the amount

of the drug in the body that has been absorbed, distributed, and eliminated.) The study will stop once the MR Prograf® (tacrolimus) is available commercially or by notification from the sponsor (Fujisawa).