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 Efficacy 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
clinic 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).