
**Serious and Other Selected Adverse Events
Reported for Human Gene Transfer Protocols
Recombinant DNA Advisory Committee Meeting
December 2010**

Protocol Number: **530**

Protocol Title: **A Randomized, Phase II/III Study of TNFerade™ Biologic with 5-FU and Radiation Therapy for First-Line Treatment of Unresectable Locally Advanced Pancreatic Cancer.**

DocID#	Receipt Date	Event Description
10941	07/28/2010	Subject was admitted for diarrhea and subsequent dehydration about a week after the fourth dose of the study agent. This was likely due to the chemotherapy and radiation that accompanies administration of the study agent.
10942	07/28/2010	The subject developed pancreatitis after having a bile duct stent was placed. This occurred about a month after the last dose of the study agent. It is possible that injection of the study agent into the tumor may have contributed to this inflammation.
10943	07/28/2010	Subject developed a fever shortly after the fifth dose of the study agent. Subject recovered and no source of infection was found.

Protocol Number: **585**

Protocol Title: **A Phase I Study of Sequential Vaccinations with Fowlpox-CEA(6D)-TRICOM (B7.1/ICAM/LFA3) and Vaccinia-CEA(6D)-TRICOM, in Combination with GM-CSF and Interferon-Alfa-2B in Patients with CEA Expressing Carcinomas.**

DocID#	Receipt Date	Event Description
10989	09/16/2010	One month after administration of the gene transfer the subject's blood test showed an elevation above the baseline value in creatinine phosphokinase, a marker of muscle inflammation. It was considered a moderate elevation and it was unclear if subject had symptoms related to this finding as subject reported frequent muscle aches that were ongoing. A cardiac evaluation was done and did not reveal a cardiac etiology for this lab value. Study agent administration is being held until event is resolved.

Protocol Number: 854

Protocol Title: **A Phase IIb, Randomised, Controlled, Open Label, Multicentre Study of the Efficacy and Safety of Trinam® (EG004); an Assessment of Vascular Access Graft Survival in Hemodialysis Patients**

DocID#	Receipt Date	Event Description
10996	09/29/2010	Subject developed a fever, as well as nausea and vomiting, shortly after administration of the gene transfer agent. The adenoviral vector was detected in the subjects serum but no replicating adenovirus was detected. The symptoms resolved.

Protocol Number: 947

Protocol Title: **A Randomized Phase 3 Clinical Trial to Evaluate the Efficacy and Safety of a Treatment with OncoVEXGM-CSF Compared to Subcutaneously Administered GM-CSF in Melanoma Patients with Unresectable Stage IIIb, IIIc and IV Disease**

DocID#	Receipt Date	Event Description
10935	07/27/2010	Three weeks after receiving the fourth dose of the study agent, the subject was admitted to the hospital for a surgical consultation due to gastrointestinal bleeding. A metastatic melanoma was found in the colon and removed.
11012	10/26/2010	Subject was admitted to hospital with fever, swelling and redness of the leg. Diagnosis was metastatic melanoma lesion with overlying cellulitis. Subject had received injection into that area of the leg. Infection improved with antibiotics and subject recovered.

Protocol Number: 998

Protocol Title: **Administration of anti-CD19-Chimeric-antigen-receptor-transduced T cells from the original transplant donor to patients with recurrent or persistent B-cell malignancies after allogeneic stem cell transplantation**

DocID#	Receipt Date	Event Description
11008	09/17/2010	Six days after receiving the gene modified T cells, the subject became febrile and than developed fatigue, lethargy and fevers. This progressed by day seven to include dyspnea, low blood oxygen levels, rapid heart rate and lower blood pressure than normal. Subject was admitted to the intensive care unit and an echocardiogram of the heart revealed a low left ventricular ejection fraction compared to baseline echocardiogram done five months previously. The etiology of this event could be infection leading to sepsis or elevation in cytokines secondary to a reaction to the gene modified T cells. At the time of the report, subject had stabilized although the cardiac function had not recovered and was being transferred out of the intensive care unit. Of note the subject did not require mechanical ventilation (i.e. a breathing tube) or medications to support his blood pressure.