Serious and Other Selected Adverse Events
Reported for Human Gene Transfer Protocols
Recombinant DNA Advisory Commitee Meeting
June 2004

Protocol Number: **274**

Protocol Title: **A Phase I, Multi-Center, Open Label, Safety and Tolerability Study of Increasing Single Dose of NV1FGF Administered by Intra-Muscular Injection in Patients with Severe Peripheral Artery Occlusive Disease.**

DocID#	Receipt Date	Event Date	Event Description
6095	03/19/2004	Unknown	Sponsor reported that subject expired, but the exact date of death was not reported and the investigator was not aware of the subject's death. This is the European study. This is the same subject with Merkel cell carcinoma as in previous reports DocID# 5566, 5611, and 5630.
6100	03/25/2004	03/08/2004	Subject was treated with blinded study agent in Germany. Experienced increase of pain likely due to an infection. The increase in pain was considered not related to study medication, rather to the underlying or concomitant illness. Due to an increase in pain in the study leg with redness and swelling, phlebography was performed which diagnosed a deep vein thrombosis (DVT). Treated with enoxaparin SC. The DVT was considered by Investigator as related to study medication. Case was unblinded, but this report did not specifically state which agent was received.
6109	03/31/2004	03/08/2004	Follow up Sponsor: Lists the suspected cause of the event of deep vein thrombosis (DVT)as "study medication and study procedure." States subject has a history of femoropopliteal artery bypass in the leg. It is not clear whether the subject got the active agent, but it does list the product as the NV1FGF.
6143	04/27/2004	03/08/2004	Follow up Sponsor: Subject was discharged and the deep vein thrombosis (DVT) was considered "recovered with sequelae."
6144	04/27/2004	04/14/2004	Subject experienced gangrene with sepsis. Admitted and underwent lower leg amputation. Gangrene with sepsis was considered by the Investigator to be related to the underlying/concomitant illness and not related to the study medication. Subject is in the Germany trial.

Protocol Number: **452**

Protocol Title: **A Multicenter, Randomized, Double-Blind, Placebo Controlled, Dose-Response Study to Evaluate the Efficacy and Safety of Ad5.1FGF-4 in Patients with Stable Angina.**

DocID#	Receipt Date	Event Date	Event Description
6101	03/25/2004	2004	Subject with a long history of cardiac disease was found unresponsive after apparently suffering an unwitnessed cardiac arrest. Resuscitation efforts were unsuccessful. Death was deemed "possibly" related to the study agent, but no further details are available at this time.

Protocol Number: **456**

Protocol Title: **Phase I Study of a Recombinant Fowlpox Vaccine rF-CEA(6D)/TRICOM alone or with GM-CSF in Patients with Advanced CEA Expressing Adenocarcinoma.**

DocID#	Receipt Date	Event Date	Event Description
6035	02/18/2004	02/16/2004	Subject admitted for bleeding from colostomy. No other details available at this time.

Protocol Number: **490**

Protocol Title: **A Pilot Phase I/II Study of Intranodal Delivery of a Plasmid DNA (Synchrovax SEM Vaccine) in Stage IV Melanoma Patients.**

DocID#	Receipt Date	Event Date	Event Description
6124	03/26/2004	10/18/2002	Subject had a deep venous thrombosis, considered to have a "possible" relationship to the study agent. The study agent was discontinued.

Protocol Number: **538**

Protocol Title: **A Phase I-II Trial Using Dendritic Cells Transduced with an Adenoviral Vector Containing the p53 Gene to Immunize Patients with Extensive Stage Small Cell Lung Cancer After Standard Chemotherapy.**

DocID#	Receipt Date	Event Date	Event Description
6139	04/23/2004	04/10/2004	Subject experienced generalized pain, shortness of breath and swelling post-injection of study agent. This occurred after a lengthy car ride. These events were considered to be "expected and related" following vaccination.

Protocol Number: **568**

Protocol Title: **A Phase II Multi-Center, Double-Blind, Placebo-Controlled, Trial of VLTS-589 in Subjects with Intermittent Claudication Secondary to Peripheral Arterial Disease.**

DocID#	Receipt Date	Event Date	Event Description
6102	03/25/2004	01/03/2004	Follow up Sponsor: Event of vomiting and diarrhea leading to dehydration was resolved on Study Day 37. Also reports that subject was diagnosed with adenocarcinoma of the colon and Hodgkin's disease during this admission.
6018	02/13/2004	01/12/2004	Approximately one month after receiving the investigational agent, the subject presented with hiccoughs, labored respirations, and a two week history of nausea, vomiting, and diarrhea. An extensive work-up revealed moderately differentiated adenocarcinoma of the colon and Hodgkin's disease.
6019	02/13/2004	01/12/2004	On Study Day 35 the subject was diagnosed with Stage III Hodgkin's disease and the subject was to be given chemotherapy. The Investigator considered the classic Hodgkin's as possibly related. The Sponsor disagreed, believing the temporal relationship between investigational agent administration and the diagnosis of Hodgkin's incompatible with that assessment.

Protocol Number: **571**

Protocol Title: **A Phase II Randomized Study of GM-CSF Gene-Modified Autologous Tumor Vaccine (CG8123) with and without Low-Dose Cyclophosphamide in Advanced Stage Non-Small Cell Lung Cancer.**

DocID#	Receipt Date	Event Date	Event Description
6182	04/02/2004	2003	After tumor resection surgery, subject developed significant amounts of bloody drainage from chest tube. Subject was taken back to the operating room and found to have a large bleed at the tumor resection site. Subject suffered cardiopulmonary arrest and could not be resuscitated. Final assessments of event by Investigator and study Sponsor were that the post-operative bleeding was related to the surgical tumor harvest procedure; this ultimately caused the subject's demise.