DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
10903 New Hampshire Avenue
Document Mail Center - WO66-G609
Silver Spring, MD 20993-0002

Anil Potti, MD
Institute for Genome Sciences and Policy
Division of Medical Oncology
Duke University Medical Center
Durham, NC 27705

OCT - 7 2009

Re: I090606
Phase II Prospective Study Evaluating the Role of Pemetrexed Plus Gemcitabine Chemotherapy for Chemo-naïve Select Stage IIIB and IV Non-Small Cell Lung Cancer (NSCLC) in Patients Using a Genome Predictor of Platinum-Resistance to Guide Therapy

Dear Dr. Potti:

The Center for Devices and Radiological Health (CDRH) within the Food and Drug Administration (FDA) has reviewed your submission, dated August 5, 2009, proposing a protocol for personalized treatment selection for Cisplatin resistance in NSCLC.

We have determined that if CDRH had the lead in reviewing your proposed clinical investigation, it would represent a significant risk study in accordance with the definition for a significant risk device in section 812.3(m) of the investigational device exemptions (IDE) regulation; and would require both FDA and institutional review board (IRB) approval before initiating the study. However, we believe this study is for a combination product where the Center for Drug Evaluation and Research (CDER) would be the lead Center coordinating the review with CDRH. Based on discussions with CDER, this study would require an investigational new drug (IND) for the following reasons:

1. Since a platinum drug is standard of care as first line treatment in metastatic NSCLC this study put subjects at risk of not receiving optimal care for their cancer.
2. The proposed study will not validate the genomics assay. While the investigators state that the assay has been validated in NSCLC they present no data to support their claim. To validate the assay patients with and without the genomic pattern of platinum-resistance have to receive a platinum drug.
3. Patients with predominant squamous NSCLC should not receive pemetrexed.
4. To determine whether platinum resistance confers increased sensitivity to pemetrexed/gemcitabine would also require that assay detected platinum sensitive and resistant patients both get pemetrexed/gemcitabine.

Future correspondence, including submission of IND, should be directed to:

Dr. Robert Justice, Division Director
Division of Oncology Drug Products
Food and Drug Administration
Center for Drug Evaluation and Research
Central Document Room
5901-B Ammendale Rd.
Beltsville, Md. 20705-1266

If you have questions regarding the IND process, you may contact Frank Cross Jr., Chief Project Manager, Division of Oncology Drug Products at frank.crossjr.@fda.hhs.gov or 301-796-0876. For any questions on the center assignment or general process, you may contact Dr. Patricia Love at patricia.love@fda.hhs.gov or 301-427-1934.

Please reference the CDRH PreIDE # I090606 in all future correspondences.

Sincerely yours,

Maria M Chan

Maria M. Chan, PhD
Director
Division of Immunology and Hematology Devices
Office of *In Vitro* Diagnostic Device Evaluation and Safety
Center for Device and Radiological Health

cc: Ayoub Suliman, Frank Cross Jr., Patricia Love.