

N057K: Phase I/II Evaluation of Everolimus (RAD001), Radiation and Temozolomide (TMZ)
Followed by Adjuvant Temozolomide and Everolimus in Newly Diagnosed Glioblastoma”

Status Change Notice – September 22, 2011

NOTICE OF STATUS CHANGE

This study is *temporarily* closed to patient accrual effective September 22, 2011 due to an unexpected delay in the delivery of Afinitor[®] (everolimus).investigational drug re-supply from the sponsor Novartis.

Please retain this notice with the protocol.

September 20, 2011

RE: Afinitor[®] (everolimus) Drug Re-Supply Delay for Third Party/Investigator Initiated Trials

Dear Investigator and Trial Coordinator,

Novartis Pharmaceuticals Corporation (Novartis) is writing to inform you of an unexpected delay in the delivery of Afinitor[®] (everolimus) Investigational drug re-supply. The delay is due to a regulatory request from the U.S. Food and Drug Administration related to the importation process, and we are working to resolve this issue promptly.

This delay affects all investigator initiated/third party trials, including the 2.5 mg, 5 mg and 10 mg dose strengths.

Situation Summary:

- There is a temporary shortage of drug for investigator initiated/third party studies.
- The shortage is due to a delay in delivery of everolimus Investigational drug re-supply intended to replace the everolimus 5 mg tablets that are expiring on September 30, 2011 (lot # S0009).
- We will be limiting drug re-supply to a 30 day supply at a time, for each patient.
- We will not supply drug to new patients at this time.
- All new enrollment and new site openings should be put on hold.
- This does not affect Novartis sponsored trials or patients who are prescribed commercial product.

Novartis will be sending drug supply for your ongoing patients and we will provide you with additional information as soon as it becomes available.

We urge you to temporarily hold new enrollment in your studies and not open additional sites until we notify you that additional drug supply is available. Novartis will not be distributing any supply for new trial patients at this time.

If you have any questions regarding the expiration date/lot number of Afinitor[®] (everolimus) trial drug supply at your site, please call the below Novartis contact. As a reminder, it is critical that you check the drug supply for all active patients to ensure that no patients take expired material.

If you need drug resupply please complete a drug order form and send it to the contact below. It is also important that you note on the form how many patients are currently undergoing treatment:

Kristen White, kristen.white@novartis.com, 862-778-2969.

If you have any concerns or questions please contact: Eliza Argonza-Aviles, Clinical Trial Manager, at 862-778-6991 (eliza.argonza-aviles@novartis.com).

Sincerely,


Jaqueline Rogerio, MD
Medical Director, Afinitor[®] Medical Affairs Program
US Clinical Development and Medical Affairs