

North Central Cancer Treatment Group

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

Update 1 – March 13, 2009

**Summary**

- Administrative/editorial changes.

**Replacement pages are included. Please incorporate into the protocol and keep this addendum with your protocol.**

**Title page** Updated to reflect the addition of Update 1 and revised NCI version date.

**Protocol Resource Page**

Page 2: The information for the “Paraffin-embedded tissue pathology” contact has been revised from Christine Maszk to Helen Tollefson.

**Section 7.0 Protocol Treatment**

Page 26:

In Section 7.122, the dose level instruction in the table for cycle 3 everolimus has been revised for editorial correction. Text has been added in the “Cycle 4-8” and “Cycle 9+” for editorial corrections/clarification. Changes are as follows:

	Agent	Dose Level	Route	Day(s)	ReRx
Adjuvant treatment with everolimus and temozolomide.					
Cycle 3:	Everolimus*	<del>Call Registration Office for assigned dose level—may be different from everolimus dose used in concomitant treatment.</del> <b>Same dose level as in cycle 1</b>	Oral	1, 8, 15 and 22	28 days
	Temozolomide**	150 mg/m <sup>2</sup> /d	Oral	1-5	28 days
Cycles 4-8	Everolimus	<del>Same D</del> <b>Same</b> dose level as in cycle 3	Oral	1, 8, 15, and 22	28 days
	Temozolomide	200 mg/m <sup>2</sup> /d***	Oral	1-5	28 days
Adjuvant treatment with everolimus alone until progression <sup>1</sup>					
Cycles 9+:	Everolimus*	Same as <b>adjuvant treatment dose</b> above	oral	1, 8, 15 and 22	28 days

Pages 28: In Section 7.211, the word “same” has been added to the dose level column in cycle 4-8 for an editorial correction, as follows:

	Agent	Dose Level	Route	Day(s)	ReRx
Adjuvant treatment with everolimus and temozolomide for 6 cycles					
Cycles 3:	Everolimus*	Dose level as determined in PHASE I	Oral	1, 8, 15 and 22	28 days
	Temozolomide**	150 mg/m <sup>2</sup> /d	Oral	1-5	28 days
Cycles 4-8:	Everolimus*	<del>Same D</del> <b>Same</b> dose level as in cycle 3	Oral	1, 8, 15 and 22	28 days
	Temozolomide**	200 mg/m <sup>2</sup> /d***	Oral	1-5	28 days
Adjuvant treatment with everolimus alone until progression <sup>1</sup>					
Cycles 9+:	Everolimus*	Same as adjuvant treatment dose above	Oral	1, 8, 15 and 22	28 days