I1

Radiation Therapy Oncology Group
Phase I/II Trial of Concurrent RAD001 (EVEROLIMUS) with Temozolomide/Radiation Followed by Adjuvant RAD001/Temozolomide in Newly Diagnosed Glioblastoma
Initial Evaluation Form

RTOG Study No 0913 Case #

PLACE LABEL HERE

Institution Name Institution No.
Patient Initials Patient Study No.

AMENDED DATA ☐ YES

INSTRUCTIONS: Submit this form at protocol entry. Dates are recorded as mm-dd-yyyy unless otherwise specified.

GENERAL INFORMATION

1 (1)___ **AGE**

2 (2)___ **KARNOFSKY PERFORMANCE STATUS (0-100)**

3 (3)___ **NEUROLOGIC FUNCTION**
- 0 No neurologic symptoms; fully active at home/ work without assistance
- 1 Minor neurologic symptoms; fully active at home/ work without assistance
- 2 Moderate neurologic symptoms; fully active at home/ work but requires assistance
- 3 Moderate neurologic symptoms; less than fully active at home/ work and requires assistance
- 4 Severe neurologic symptoms; totally inactive requiring complete assistance at home or in institution; unable to work

DISEASE INFORMATION

4 (4)___-___-___ **DATE OF INITIAL PATHOLOGIC DIAGNOSIS**

(5)___ **EXTENT OF RESECTION**
- 1 Not applicable
- 2 Subtotal
- 3 Total (gross)
- 9 Other specify _____(6)

(7)___-___-___ **Date of resection**

5 (8)___ **CENTRAL PATHOLOGY CONFIRMED GBM/ GLIOSARCOMA**
- 1 No
- 2 Yes

(9)___ **SUFFICIENT TISSUE FOR MGMT/MOLECULAR PROFILE ANALYSIS**
- 0 Not applicable (Phase I only)
- 1 Usable
- 2 Inadequate

6 PRE-STUDY SCANS

	ENHANCING PRE-OP	ENHANCING POST-OP
IMAGE DATE	(10)___-___-___	(15) ___-___-___
ASSESSMENT TYPE 1 MRI scan 2 CT scan 3 Other, specify	(11)___ (12)_____	(16)___ (17)_____
Dimension 1	(13)___.___ mm	(18)___.___ mm
Dimension 2	(14)___.___ mm	(19)___.___ mm

7 SITE OF LESION
- 1 No
- 2 Yes

(20)___ Frontal
(21)___ Temporal
(22)___ Parietal
(23)___ Occipital
(24)___ Basal Ganglia
(25)___ Cerebellum
(26)___ Brainstem
(27)___ Corpus Callosum
(28)___ Spinal Cord
(29)___ Other, Specify (30) _____

8 (31)___ **TUMOR LATERALITY**
- 1 Right
- 2 Left
- 3 Bilateral
- 9 Unknown

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9 BASELINE LABS

A BONE MARROW FUNCTION

(32) **ANC** ___ cells/mm³

(33) Date _____-_____-_____

(34) **PLATELETS** ___ cells/mm³

(35) Date _____-_____-_____

(36) **HEMOGLOBIN** ___.___ g/dl

(37) Date _____-_____-_____

(38) **WBC** ___ cells/mm³

(39) Date _____-_____-_____

B RENAL FUNCTION

(40) **BUN** ___.___ mg/dl

(41) Date _____-_____-_____

(42) **SERUM CREATININE** ___.___ mg/dl

(43) Date _____-_____-_____

C HEPATIC FUNCTION

(44) **TOTAL BILIRUBIN** ___.___ mg/dl

(45) Bilirubin ULN ___ mg/dl

(46) Date _____-_____-_____

(47) **ALT** ___.___ u/L

(48) ALT ULN ___ u/L

(49) Date _____-_____-_____

(50) **AST** ___.___ u/L

(51) AST ___ u/L

(52) Date _____-_____-_____

D COAGULATION TIME

(53) **PTT** ___.___

(54) **INR** ___.___

(55) Date _____-_____-_____

E FASTING CHOLESTEROL

(56) ___ **mg/dl**

or

(57) ___.___ **mmol/L**

(58) Date _____-_____-_____

F TRIGLYCERIDES

(59) ___ **mg/dl**

or

(60) ___.___ **mmol/L**

(61) Date _____-_____-_____

(62) ☐ **HAS THE PATIENT TAKEN ANTICOAGULANT AGENTS?**

1 No
2 Yes, specify_____(63)

Date of last dose _____-_____-_____(64)

10 (65) ☐ **AGENTS WITH PROARRHYTHMIC POTENTIAL**

1 No
2 Yes, specify_____(66)

Date of last dose _____-_____-_____(67)

11 (68) ☐ **CORTICOSTEROIDS**

1 No
2 Yes, (69)____-____-____ Date of Initial Dose

Specify (70)_____

12 (71) ☐ **ANTICONVULSANTS**

1 No
2 Yes, (72)____-____-____ Date of Initial Dose

Specify (73)_____

(74) ☐ **EIAEDS** (75)_____-_____-_____ Date of last dose

(76) ☐ **NEIAEDS** (77)_____-_____-_____ Date of last dose

1 No
2 Yes

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13 SEVERE ACTIVE COMORBIDITY
(see section 3.2 of protocol)
1 No
2 Yes

(78)____ Unstable angina

(79)____ Transmural myocardial infarction

(80)____ Infection

(81)____ Cerebrovascular accident (including stroke)

(82)____ Peripheral vascular disease (PVD)

(83)____ Coagulation defects

(84)____ AIDS

(85)____ Significant vascular disease
(e.g. Aortic Aneurysm, aortic dissection)

(86)____ Serious non-healing wound

(87)____ Symptomatic congestive heart failure

(88)____ Uncontrolled cardiac arrhythmia

(89)____ Severely impaired lung function

(90)____ Uncontrolled diabetes

(91)____ Active (acute or chronic) or uncontrolled severe infection

(92)____ Liver disease

(93)____ Active connective tissue disorders

(94)____ History of deep vein thrombosis or pulmonary embolism

(95)____ Impairment of gastrointestinal function or gastrointestinal disease

(96)**Comments:** _____

_____

_____

_____

(97) **Completed by**_____ (98)**Form completion date, original**____-____-_____