UCI 趙 Chao Family Comprehensive Cancer Center

Neuro-Oncology Disease-Oriented Team

Clinical Research Treatment Trial Flowchart

Glioblastoma

Newly Diagnosed

NRG-BN011

MGMT methylated only, IDH WT, surgery required, no biopsy, tissue to NRG ≤ 30 days from DOS; age 18-70

Randomized 1:1: RT+TMZ vs RT+TMZ+CCNU

Mechanism: Alkylating Chemotherapy

Coord: Tatsuya Tojima
Accrual: 6/8

UCI 23-198

Methylated and unmethylated; IDH WT; Biopsy ok; Leptomeningeal disease ok***; IV medication

Randomized: $NaNO_2$ vs Placebo

Mechanism: A High-Capacity Oxygen Carrier/radiosensitizer

Coord: Tatsuya Tojima
Accrual: 1/6

Open to Accrual | Low Accruing | Pending Activation/Suspended

Glioblastoma

Recurrent

2nd line

UCI 24-27 (opened 12/03/24)

Enrolling in Phase II
Randomized: NMS-03305293(IP)+ TMZ 7/28 day vs 28/28 day

1st recurrence only, measurable disease required even after surgery; IDH WT; multifocal disease allowed.

Mechanism: PARP-1 inhibitor

Coord: Tatsuya Tojima

2nd line

UCI 24-39
Phase 1B
Open label: require surgical resection; IDH WT; multifocal disease not allowed.

Mechanism: Dual Gene Therapy/immunotherapy

PRMC approved w/stipulations; pending activation

2+ lines

UCI 23-67 (Screening 01 temporarily suspended)
Open label monotherapy

Eligible histologies include:
- astrocytoma IDH mutant Grade 2-4
- oligodendroglioma IDH mutant, 1p19q co-deleted Grade 2-3
- GBM

Phase 1 (intermittently closed for analysis); DLL3 > 50% expressed; multifocal disease allowed; any number of recurrence ok, prior bevacizumab washout 6 months.
Mechanism: humanized IgG-like T cell engager, targets DLL3 cells

Coord: Daniel Na
Accrual: 1/5

Open to Accrual | Low Accruing | Pending Activation/Suspended

Low Grade Glioma

Newly Diagnosed

Recurrent

UCI 23-67 (Screening 01 temporarily suspended)

Open label monotherapy

Eligible histologies include:

- astrocytoma IDH mutant Grade 2-4
- oligodendroglioma IDH mutant, 1p19q co-deleted Grade 2-3
- GBM

Phase 1 (intermittently closed for analysis); DLL3 > 50% expressed; multifocal disease allowed; any number of recurrence ok, prior bevacizumab washout 6 months.

Mechanism: humanized IgG-like T cell engager, targets DLL3 cells

Coord: Daniel Na

Accrual: 1/5

Open to Accrual | Low Accruing | Pending Activation/Suspended

Newly Diagnosed

UCI 22-83

H3K K27M mutant diffuse glioma; IP starts in adjuvant phase (2-6 weeks post RT); oral
Randomized 1:1:1: ONC201 vs Placebo

Mechanism: DRD2 dopamine receptor antagonist

Coord: Tatsuya Tojima
Accrual: 2/4

Open to Accrual | Low Accruing | Pending Activation/Suspended

Meningioma

Newly Diagnosed

Recurrent

A071401
Only AKT1/PIK3CA/PTEN arm open

Mechanism: blocking signaling through the AKT cellular survival pathway, leading to inhibition of cell proliferation and increased apoptosis

Coord: Daniel Na
Accrual: 2/3

ETCTN 10186 (temporarily suspended)
Phase II: Nivo + Ipi + Radiosurgery

Meningioma grade II and III

Mechanism: PD-1 Inhibitor + CTLA-4 inhibitor

Coord: Tatsuya Tojima

Accrual: 1/4

Open to Accrual | Low Accruing | Pending Activation/Suspended

1st line

NRG BN013

Phase III: Single fraction Stereotactic Radiosurgery (SRS) vs Fractionated Stereotactic Radiosurgery (FSRS)

Eligible histologies within 5 years of registration:
- NSCLC m
- Melanoma
- Breast cancer
- RCC
- Gastrointestinal cancer

At least 1 and upto 8 intact brain mets; needs measurable disease: ≥ 1.0 cm and ≤ 3.0 cm; all mets must be located outside of brainstem and
≥5 mm from the optic nerves or optic chiasm and ≤ 3.0 cm in maximum dimension; no known leptomeningeal disease; no prior radiotherapy to the brain.

Pending activation

2nd line

NRG BN012

Phase III: Pre-operative Stereotactic RT vs Post-operative Stereotactic RT

1-4 lesions allowed with 1 requiring resection; prior RT or SRS to resection site is not allowed but prior SRS to other lesions allowed; known active/history of non-CNS primary cancer within 3 years (excludes germ cell tumor, SCC or lymphoma).

Mechanism: stereotactic radiosurgery

Coord: Daniel Na

Accrual: 4/6

Open to Accrual | Low Accruing | Pending Activation/Suspended

Newly Diagnosed