

# Neuro-Oncology Disease-Oriented Team

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Clinical Research Treatment Trial Flowchart

## Newly Diagnosed

### NRG-BN011

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

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

Mechanism: Alkylating Chemotherapy

Coord: Daniel Na  
Accrual: 6/8

### UCI 23-198

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

Randomized (2:1): NaNO<sub>2</sub> vs Placebo

Mechanism: A High-Capacity Oxygen Carrier/radiosensitizer

Coord: Manisha Dandekar  
Accrual: 2/6

## Recurrent

### 2<sup>nd</sup> line

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

**Enrolling in Phase I currently (currently suspended: Astrocytoma grade 3 and 4 only)**

**Phase 2 for GBM only (currently suspended)**

Randomized: NMS-03305293(IP)+ TMZ 7/28 day vs 28/28 day

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

Mechanism: PARP-1 inhibitor  
Coord: Daniel Na

#### UCI 24-39

##### **Phase 1B**

Open label: require surgical resection; IDH WT; multifocal disease not allowed.

Mechanism: Dual Gene Therapy/immunotherapy

PRMC approved; IRB approval, awaiting grant and activation

Open to Accrual

Low Accruing

Pending Activation/Suspended

### 2+ lines

#### UCI 23-67 (Screening 01 temporarily suspended)

##### **Phase 1 Open label monotherapy**

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;  
histologies: astrocytoma, oligodendroglioma and GBM

Coord: Daniel Na  
Accrual: 2/5

#### ETCTN 225Ac phase I- Immunotherapy

##### **Phase 1**

Early stage in ETCTN pipeline, protocol not available, DOT approved on 01/03/2025

Must be surgical candidates; ECOG 0-2, 1<sup>st</sup> or 2<sup>nd</sup> relapse; measurable disease required; last RT ≥182 days; ≤2mg dexamethasone within 2 weeks of start

#### ETCTN 10699

##### **Phase 1**

Awaiting final protocol, DOT approved on 03/07/2025, will activate June 2025

## Newly Diagnosed

## Recurrent

### UCI 23-67 (Screening 01 temporarily suspended)

#### Phase 1 Open label monotherapy

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;  
histologies: astrocytoma, oligodendroglioma and GBM

Coord: Daniel Na

Accrual: 2/5

### UCI 25-69

#### DOT approved on 5/3/25 pending activation

Phase 1, DDI sub-study then patients will get Olutasidenib as compassionate use

0/5

## Newly Diagnosed

### UCI 22-83

(Temporarily suspended as of 2/28/25)

Phase III; H3 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: Manisha Dandekar

Accrual: 2/4

## Newly Diagnosed

■ Open to Accrual ■ Low Accruing ■ Pending Activation/Suspended

## 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: 3/6

1<sup>st</sup> lineNRG 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:  $\geq 1.0$  cm and  $\leq 3.0$  cm; all mets must be located outside of brainstem and  $\geq 5$  mm from the optic nerves or optic chiasm and  $\leq 3.0$  cm in maximum dimension; no known leptomeningeal disease; no prior radiotherapy to the brain.

Coord: Daniel Na  
Accrual: 0/5 (open in Dec 2024)

2<sup>nd</sup> lineNRG 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: 5/6

**UCI 23-199**

TLX101-CDx (18F-FET): radiopharmaceutical tracer  
To differentiating recurrence versus pseudoprogression in gliomas  
(all grades)

Dose 5mCi +/-10%.; 30 days washout for experimental drugs

Coord: Sherin Mathew  
10/10



## UCI 24-82

NF1 mut solid tumors including but not limited to nerve sheath tumors, gliomas, malignant melanoma, breast cancer and others; however, **NF1 is not open currently.**

Local testing; contact CRC for specific tumor types

Coord: Connie Kang  
Accrual: 6/10

## **UCI 24-197**

**(DOT approved on 01/08/25)**

Phase I/II; MTAP-loss; GBM patients in dose expansion cohort only

TNG456 monotherapy and TNG456+abemecicli arms

Accrual: 0/5