

Neuro-Oncology Disease-Oriented Team

Clinical Research Treatment Trial Flowchart

New Studies in Pipeline	PI	Latest Status
UCI 24-39 (IIT): Phase IB, Open-Label Trial of Dual Cytotoxic and Immune-stimulatory Gene Therapy in Combination with G-CSF for the Treatment of Resectable, Recurrent Glioblastoma (GBM)	Dr. Bota	DOT approved 3/1/24 PRMC approved 8/1/24 IRB approved 5/8/26 Pending clarification of IP shipping status, SIV, and funding to proceed
ETCTN 10713: A Phase I Trial of 225Ac-anti-CD33 and PD1-inhibitor in Recurrent Glioblastoma	Dr. Lomax	DOT approved 1/3/25 Study opened in Mar2026 (not at our site), but delayed for another 6 months from consortium
UCI 25-151: (IIT) A Phase II Study of Elderly and Frail Patients with Newly Diagnosed or Recurrent Malignant Glioma Treated with Cesium-131 GammaTile® (ENDURANCE Trial)	Dr. Yuen	DOT approved on 10/3/25 PRMC approved 2/3/26 IRB approved 7/10/26
UCI 25-93: A Prospective, Single-Arm Study of a Modified Lumbar Puncture (LP) Procedure that Reduces Post-Lumbar Puncture Headaches (PLPH) in Adult Neuro-Oncology Patients	Dr. Kong	DOT approved on 2/6/26, Manisha reached out to sponsor to add UCI as a site before submitting to IRB
UCI-26-34: A Phase II Randomized, Multicenter Study to Evaluate the Efficacy and Safety of Silevertinib, an Oral EGFR Inhibitor, in Combination with Temozolomide in Patients with Newly Diagnosed Glioblastoma with Unmethylated MGMT Promoter and EGFRvIII	Dr. Bota	DOT approved on 2/06/26 Submitted to WCG on 04/28/26 PRMC approved on 05/08/26, SIV scheduled on 09/25/26

UCI 26-34*: Silevertinib, (EGFR Inhibitor) + Temozolomide

Phase II, part 2 only- investigational treatment given during adjuvant treatment not concomitant treatment

Randomized open label; unmethylated GBM Harboring EGFRvIII mutation;
1:1 randomized Arm A: Silveretinib+TMZ Arm B TMZ monotherapy

PI: Dr. Bota

DOT approved on 02/06/26, PRMC approved on 05/05/26, pending **SIV on 09/25/26**

NRG-CC017: Temporally-modulated Pulsed Radiation Therapy (TMPRT) vs. Standard RT + Temozolomide (Open in Irvine as of 9/1/26)

Phase III, randomized (1:1); Newly diagnosed Unmethylated MGMT only;
English and French patients only

Arm1: RT + concomitant and adjuvant TMZ

Arm2: Temporally Modulated Pulse RT + concomitant and adjuvant TMZ

PI: Dr. Kong

Pending SIV

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

* Only consent in Irvine

** Consent and Tx in Irvine

UCI 25-151: Cesium-131 GammaTile®

ENDURANCE Trial, Ph 2: GammaTile: Elderly and Frail Patients with ND GBM/rGBM or recurrent glioma

Arm A: Newly diagnosed;

Arm B: Recurrent Elderly or Frail Glioblastoma;

Arm C: Newly Diagnosed Frail (non-GBM) Malignant Glioma;

Arm D: Recurrent Frail (non-GBM) Malignant Glioma;

PI: Dr. Yuen; Co-I: Dr. Hsu

DOT approved 10/3/25, PRMC approved 2/3/26, IRB approved 7/10/26

2nd line

UCI 24-39**: Dual Cytotoxic and Immune-stimulatory Gene Therapy + G-CSF

Phase 1B

Open label: require surgical resection; IDH WT; multifocal disease not allowed; 1st recurrence only.

Mechanism: Dual Gene Therapy/immunotherapy

PI: Dr. Bota

Initial IRB approval, pending activation. Gene therapy in Irvine only.

A072201**: Anti-Lag-3 and Anti-PD-1 Blockade vs. SOC (SUSPENDED for data analysis and modification)

Phase II, randomized study, 1st recurrence

Arm 1: Relatlimab + Nivo; Arm 2: CCNU

PI: Dr. Choi

Coord: Katia Talamantez
1/5

UCI 25-151: Cesium-131 GammaTile®

ENDURANCE Trial, Ph 2: GammaTile: Elderly and Frail Patients with ND GBM/rGBM or recurrent glioma

Arm A: Newly diagnosed;

Arm B: Recurrent Elderly or Frail Glioblastoma; 2nd and 2+ lines of tx

Arm C: Newly Diagnosed Frail (non-GBM) Malignant Glioma;

Arm D: Recurrent Frail (non-GBM) Malignant Glioma;

PI: Dr. Yuen; Co-I: Dr. Hsu

DOT approved 10/3/25, PRMC approved 2/3/26, IRB approved 7/10/26

2+ lines

ETCTN 10713: 225Ac-anti-CD33 and PD1-inhibitor

Activation timeline- July-August 2026

Immunotherapy; Phase 1; Must be surgical candidates; ECOG0-2, 1st or 2nd relapse; measurable disease required; last RT ≥182 days; ≤2mg dexa within 2 weeks of start

PI: Dr. Lomax

ETCTN 10699**: Triapine + RT (no slots as of 8/5/26)

Phase 1 open label combining Triapine and RT

Ribonucleotide reductase regulatory subunit 2 (RRM2) inhibitor; candidates for re-irradiation; GBM and variants IDH WT grade 2-4, Astrocytoma IDH mut grade 2-4, Diffuse midline glioma including pediatric-type H3K G34 or E3 K27

PI: Dr. Lomax
Coord: Sabrina Beltran
2/5

Newly Diagnosed

A072301**: RT + Temozolomide + Vorasidenib (IDH Inhibitor) vs Placebo

Phase III randomized (1:1), double blinded trial for Astrocytoma Grade 3

Arm1: TMZ+Placebo (control); Arm2: TMZ+Vorasidenib (INV)

PI: Dr. Kong

Coord: Raufu Onayemi

1/6

UCI 25-69: Olutasidenib

Phase 1, IDH inhibitor, DDI sub-study for cycle 1; patients will then get IP (Olutasidenib) via compassionate use after DDI substudy completion

IDH1m+ malignancies (e.g. AML, gastrointestinal [GI] cancers, glioma)

PI: Dr. Yuen

Coord: Katia Talamantez

10/11

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

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** Consent and Tx in Irvine

Recurrent

UCI 25-151: Cesium-131 GammaTile®

ENDURANCE Trial, Ph 2: GammaTile: Elderly and Frail Patients with ND GBM/rGBM or recurrent glioma

Arm A: Newly diagnosed;

Arm B: Recurrent Elderly or Frail Glioblastoma;

Arm C: Newly Diagnosed Frail (non-GBM) Malignant Glioma;

Arm D: Recurrent Frail (non-GBM) Malignant Glioma;

PI: Dr. Yuen; Co-I: Dr. Hsu

DOT approved 10/3/25, PRMC approved 2/3/26, IRB approved 7/10/26

Newly Diagnosed

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

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** Consent and Tx in Irvine

Recurrent

ETCTN 10699**: Triapine + RT
(no slots as of 8/5/26)

Phase 1 open label combining Triapine and RT

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PI: Dr. Lomax
Coord: Sabrina Beltran
2/5

UCI 23-67: Obrixtamig (BI 764532)
(SUSPENDED; new amd pending)

Open label monotherapy (Obrixtamig (BI 764532))

PI: Dr. Bota
Coord: Katia Talamantez
2/5

Recurrent

A071401: SMO/AKT/NF2/CDK Inhibitors**

Only AKT1/PIK3CA/PTEN and NF2, CDKN2A, CDK4, CDK6, CCND1, CCND2, CCND3 (Capivasertib 480mg), or CCNE1 (Abemaciclib 200mg) arm open

Mechanism: Capivasertib-AKT inhibitor; Abemaciclib- selective inhibitor of CDK4 and CDK6 enzymes

PI: Dr. Bota

Coord: Katia Talamantez

6/8

RTOG 3523: [177Lu] lu-dotatate

(Opened 5/19/26, SUSPENDED for amd)

Phase II; randomized, open label study of [¹⁷⁷Lu]Lu-DOTATATE; progressive intracranial grade 1-3 meningioma

Randomization (2:1): Arm A (IP) and Arm B SOC therapy

Measurable disease per RANO meningioma criteria; central confirmation of PD required; [68Ga]Ga-DOTATATE uptake on PET-CT required; option to cross over to IP arm; **Excln:** radiation associated meningioma; clinical dx or molecular dx of NF2-related schwannomatosis; prior SSTR2-targeted therapy.

Mechanism: Somatostatin receptor type 2 (SSTR2)

PI: Dr. Bota

Coord: Sabrina Beltran

0/3

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

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** Consent and Tx in Irvine

Recurrent/Refractive

UCI 25-143: Tirabrutinib vs Rituximab + Temozolomide
(Opened 06/18/26)

Open label, 2:1 randomized Tirabrutinib (480 mg) daily : R-TMZ combination

Inclusion: R/R B-Cell PCNSL with at least 1 prior HD-MTX based Tx, bidimensional measurable disease

Exclusion: Prior BTK inhibitor tx, Intraocular PCNSL w/o brain lesions, systemic lymphoma, refractory to TMZ w/wo rituximab containing regimen (ex mth-tmz-ritux)

PI: Dr. Bota
Coord: Raufu Onayemi
0/5

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

* Only consent in Irvine

** Consent and Tx in Irvine

UCI 24-197*: TNG456 +/- Abemaciclib (Slot reservation required)

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

TNG456 monotherapy and TNG456+abemacicli arms

Requires Patients to have MTAP Mutation

Patients with GBM must have had 1st or 2nd recurrence per RANO 2.0

PI: Dr. Park (Lung)

Main CRC: Cassie Smith
Neuro CRC: Katia Talamantez

Accrual: 1/5

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

* Only consent in Irvine

** Consent and Tx in Irvine

UCI 25-16*: ODM-212 (Slot reservation required) Currently enrolling Part 2 only

Part 2: Any solid tumor type harboring a Hippo pathway alteration including GBM

A fresh or recent (taken up to 1 year ago), representative tumor tissue sample (from primary tumor or from metastasis) must be available. Tissue must be a core needle biopsy, excisional or incisional biopsy. Biopsies of bone lesions that do not have a soft tissue component or decalcified bone tumor samples are also not acceptable. Exemptions possible by the sponsor's decision

PI: Dr. Dayyani (GI/HP/Panc)

Main CRC: Peter Yang
Neuro CRC: Sabrina Beltran

Accrual 13/20

UCI 25-93: Lumbar Puncture

Prospective, Single arm study of modified LP

PI: Dr. Kong
DOT approved 2/6/26

UCI 25-197: Surveillance Pilot study

Surveillance approach to local therapy in patients with Brain mets
undergoing CNS-penetrating systemic therapy

PI: Dr. Simon
CRC: Katia Talamantez
1/10

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

* Only consent in Irvine

** Consent and Tx in Irvine

UCI 24-05**: Riluzole PO vs. Placebo PO

Perceived worsening of *cognitive function*

Cohort B (prior cranial radiation) excludes high-grade glioma

PI: Dr. Chan (Clinical Pharmacy)

Primary CRC: Madeleine Phan
Neuro CRC: Sabrina Beltran
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* Only consent in Irvine

** Consent and Tx in Irvine, Laguna Hills, Yorba Linda