



	Newly Diagnosed	Recurrent/Refractory	Relapse After Radiation Therapy	Advanced	Brain Mets
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Glioblastoma

**EF-32 TRIDENT  
(Johnson/Shen)**

A Pivotal Randomized, Open-Label Study of Optune® (TTFields, 200kHz) Concomitant with Radiation Therapy and Temozolomide for the Treatment of Newly Diagnosed Glioblastoma  
**To test the effectiveness and safety of TTFields given to newly diagnosed GBM patients, concomitantly with radiation therapy and temozolomide compared to treatment with radiation therapy and temozolomide, where in both arms TTFields and maintenance temozolomide are continued following radiation therapy**  
**Planned treatment with RT/TMZ followed by TTFields and maintenance TMZ.**

**NRG-BN011** A Phase III Trial of Lomustine-Temozolomide Combination Therapy Versus Standard Temozolomide in Patients with Methylated MGMT Promoter Glioblastoma  
**No known IDH mutation.  
(If tested before step 1**

**LCCC2059-ATL  
(Cheng/Rauf)**

Phase I Study of Intraventricular Infusion of T Cells Expressing B7-H3 Specific Chimeric Antigen Receptors (CAR) in Subjects with Recurrent or Refractory Glioblastoma  
**\*Run out of CT Pod**

**SC9-GBM**

registration, patients known to have IDH mutation in the tumor on local or other testing are ineligible and should not be registered).

**Histopathologically proven diagnosis of glioblastoma (or gliosarcoma as a subtype of glioblastoma) confirmed by central pathology review**

**14379-201 (IMVAX):** A Randomized, Multicenter, Double-Blind, Placebo-Controlled, Phase 2b Study to Assess the Safety and Efficacy of IGV-001, an Autologous Cell Immunotherapy With Antisense Oligonucleotide (IMV-001) Targeting IGF-1R, in Newly Diagnosed Patients With Glioblastoma  
**Has a diagnosis of malignant glioma based on the treating neurosurgeon's best clinical judgement defined using the patient's symptomology, MRI scan results, and intraoperative frozen section verbal confirmation of malignant glioma. Verbal confirmation is defined as the pathologist's interpretation of the initial result from the flash frozen section**

**during craniotomy and verbally shared with the neurosurgeon as per SOC at the institution**

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Meningioma			<p><b><u>ETCTN10186-CIRB</u></b>  <b><u>(Johnson/Rauf)</u></b>  A Phase I/II Study of Nivolumab plus or minus Ipilimumab in Combination with Multi-fraction Stereotactic Radiosurgery for Recurrent High-grade Radiation-relapsed Meningioma  <b>Patients must have histologically confirmed WHO grade II-III meningioma which has relapsed after prior radiation therapy with radiologically progressive or recurrent disease</b></p>		
Neuroblastoma		<p><b><u>LCCC1743ATL</u></b>  <b><u>(Babinec/Hucks)</u></b>  A Phase I Study of Autologous Activated T-Cells Expressing a 2nd Generation GD2 Chimeric Antigen Receptor, IL-15, and iCaspase9 Safety Switch Administered To Patients with Relapsed/Refractory Neuroblastoma or Relapsed/Refractory Osteosarcoma  <b>*Run out of CT Pod</b>  Agent: GD2-directed CAR-T  Eligibility:</p> <ul style="list-style-type: none"> <li>- High risk neuroblastoma following completion of aggressive multi-drug frontline therapy</li> <li>- Any age</li> </ul>			

Solid Tumor

**A071701 (Johnson/Rauf)**  
Genomically-guided treatment trial in brain metastases

**This is a prospective Phase 2 study evaluating the efficacy of a CDK, PI3K or NTRK/ROS1 inhibitor in patients with progressive brain metastases harboring the alterations predicting sensitivity to each of these inhibitors**

Breast: Genetic testing in guiding treatment; HER2+, received prior HER2 directed therapy in metastatic setting; abemaciclib, entrectinib, GDC-0084

**NCI-CT018-10129-CIRB (Johnson/Rauf)**

A Phase 2 Study of PARP Inhibitor Olaparib (AZD2281) in IDH1 and IDH2 Mutant Advanced Solid Tumors **To estimate the overall response rates of olaparib in subjects with recurrent/progressive IDH1/2-mutant solid tumors, who will be recruited to 3 cohorts: glioma, cholangiocarcinoma, and other solid malignant tumors**

**Patients will be classified into the mutant IDH1/2**

					<b>inhibitor naive sub-cohort or exposed sub-cohort</b>
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NSCLC					
Breast					<p><b><u>BRE 18-360</u></b>  <b><u>(Johnson/Shen)</u></b>  Phase I/II Study of Stereotactic Radiosurgery with Concurrent Administration of DNA Damage Response (DDR) Inhibitor (Olaparib) Followed by Adjuvant Combination of Durvalumab (MEDI4736) and Physicians Choice Systemic Therapy in Subjects with Breast Cancer Brain Metastases  <b>Subject has histologically confirmed diagnosis of breast cancer (triple negative, or HER2-negative with germline or somatic BRCA mutation) and subject has new diagnosis of brain metastasis by MRI, amenable to stereotactic radiosurgery (SRS) (up to 10 metastases with total brain metastases volume ≤15cc). Patients are permitted to have undergone recent</b></p>

					<p><b>craniotomy and resection of metastasis/metastases if at least 1 other intact metastasis planned for definitive SRS is present. Discrete dural lesions are allowed.</b></p>
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Phase I

**TAPUR**  
**(Cole/Patel)**

Testing the Use of Food and Drug Administration (FDA) Approved Drugs That Target a Specific Abnormality in a Tumor Gene in People With Advanced Stage Cancer (TAPUR)

**All advanced solid tumors**

**\*Run out of Phase I pod**

**Link to available cohorts:**

[https://old-prod.asco.org/sites/new-www.asco.org/files/content-files/research-data/documents/Public-facing\\_Coho](https://old-prod.asco.org/sites/new-www.asco.org/files/content-files/research-data/documents/Public-facing_Coho)

[rt Report.pdf](#)

**APL-101-01**  
**(Cole/Dees)**

Phase 1 / 2  
Multicenter  
Study of the  
Safety,  
Pharmacokin  
etics, and  
Preliminary  
Efficacy of  
APL-101 in  
Subjects with  
Non-Small  
Cell Lung  
Cancer with  
c-Met EXON  
14 skip  
mutations  
and c-Met  
Dysregulatio  
n Advance  
Solid Tumors  
**Cohort E:**  
**CNS**  
**disease**  
**\*Run out of**  
**Phase I pod**

Translational	<p><b><u>LCCC 2212</u></b>  <b><u>(Satterlee/Devin McCarthy)</u></b>  A feasibility study to determine if a novel patient-derived explant platform can produce drug sensitivity scores within a clinically relevant time frame in patients with CNS tumors  <b>Key Eligibility:</b></p> <ul style="list-style-type: none"> <li>• A diagnosis of a tumor residing in the CNS with SOC plan to have surgical resection.</li> </ul>				
	Contacts				
					<b>Neuro:</b> <b>Meg Laffan, CRM –</b> <a href="mailto:megan_laffan@med.unc.edu">megan_laffan@med.unc.edu</a> , 984-215-4982  <b>Camisha Johnson, SC-</b> <a href="mailto:camisha_johnson@med.unc.edu">camisha_johnson@med.unc.edu</a> , 919-445-4847 (phone), 919-393-2713 (pager)  <b>Emmie Cole, Ph 1 SC</b> <a href="mailto:Emmie_cole@med.unc.edu">Emmie_cole@med.unc.edu</a> <u>u</u>  <b>Devin McCarthy, SC</b> <a href="mailto:Devin_mccarthy@med.unc.edu">Devin_mccarthy@med.unc.edu</a>