NBTS Brain Tumor Clinical Trials Report
Q2 2018

New brain tumor clinical trials open around the country all the time, and it can be hard for patients and care-partners to keep track of new opportunities to potentially participate in leading-edge clinical research. This report, generated by the National Brain Tumor Society, provides you with a summary of clinical trials that have started or begun recruitment since our last quarterly report*. Now you can identify new trials that are enrolling volunteers to more effectively evaluate how clinical research fits into your ongoing treatment plan. To learn more about the trial and contact the party responsible for enrolling patients, just follow the link provided under the brief description of each listing.

For a more comprehensive list of ALL open brain tumor clinical trials, please visit the NBTS Clinical Trial Finder at trials.braintumor.org, where you can search potential opportunities for enrollment based on criteria important and specific, to you.

- **Local Control, Quality of Life and Toxicities in Adults With Benign or Indolent Brain Tumors Undergoing Proton Radiation Therapy**
  - *Brief Description*: This research study is studying Proton Radiation as a possible treatment for brain tumor. Specifically, the trial will evaluate how well the tumor is responding to the Proton Radiation up to 5 years after the participant receive it. The investigators are also looking for how this type of radiation affects the quality of life as well as any type of side effect the participant may have after the radiation is administered.

- **[18F]Fluciclovine and [18F]FLT PET/CT Assessment of Primary High-Grade Brain Tumors**
  - *Brief Description*: A Phase II clinical trial in patients with high-grade primary brain tumors who receive chemoradiation, evaluating whether using the PET imaging agents [18F]Fluciclovine and/or [18F]FLT will be a better predictor of tumor response than standard MRI based brain tumor response criteria.

- **A First in Human Study Using 89Zr-cRGDY Ultrasmall Silica Particle Tracers for Malignant Brain Tumors**
- **Brief Description:** A Phase I clinical trial to test PET scans using 89Zr-DFO-cRGDY-PEG-Cy5-C' dot particles, can be used to take pictures of brain tumors
  - **LINK:** [https://bit.ly/2sYmE04](https://bit.ly/2sYmE04)

- **Dual-Energy CT on Plan Quality, Dose-Delivery Accuracy, and Simulated Patient Outcomes for Locally Advanced Lung and Brain Tumor Patients Treated With Proton Therapy**
  - **Brief Description:** A Phase I clinical trial to refine the accuracy of proton beam therapy (PT) by the use of dual energy computed tomography (DECT), in conjunction with novel iterative image reconstruction algorithms, to more precisely determine the tissue properties through which the proton beam path travels.
  - **LINK:** [https://bit.ly/2y5ca4V](https://bit.ly/2y5ca4V)

- **A Longitudinal Assessment of Tumor Evolution in Patients With Brain Cancer**
  - **Brief Description:** A Phase I study to test the safety and tolerability of nivolumab or nivolumab plus ipilimumab when used following surgery and before standard therapy with radiation and temozolomide in patients with newly diagnosed glioblastoma.
  - **LINK:** [https://bit.ly/2t256QL](https://bit.ly/2t256QL)

- **SJDAWN: St. Jude Children’s Research Hospital Phase 1 Study Evaluating Molecularly-Driven Doublet Therapies for Children and Young Adults With Recurrent Brain Tumors**
  - **Brief Description:** A Phase I clinical trial to perform a limited dose escalation study of multiple doublets to evaluate the safety and tolerability of these combinations followed by a small expansion cohort to detect preliminary efficacy. In addition, a more extensive and robust molecular analysis of all the participant samples will be performed as part of the trial such that we can refine the molecular classification and better inform on potential response to therapy.

- **Panitumumab-IRDye800 in Diagnosing Participants With Malignant Glioma Undergoing Surgery**
  - **Brief Description:** A Phase I/II trial to study the side effects and best dose of panitumumab-IRDye800 in diagnosing participants with malignant glioma who undergo surgery. Panitumumab-IRDye800 can attach to tumor cells and make them more visible using a special camera during surgery, which may help surgeons better distinguish tumor cells from normal brain tissue and identify small tumors that cannot be seen using current imaging methods.
- **Pembrolizumab and Vorinostat Combined With Temozolomide for Newly Diagnosed Glioblastoma**
  - Brief Description: A Phase I clinical trial to test the safety and tolerability of the combination treatment of the investigational drugs vorinostat and pembrolizumab, in combination with chemotherapy (temozolomide), and radiotherapy.

- **[18F]DASA-23 and PET Scan in Evaluating Pyruvate Kinase M2 Expression in Patients With Intracranial Tumors or Recurrent Glioblastoma and Healthy Volunteers**
  - Brief Description: A Phase I trial to study how well [18F]DASA-23 and positron emission tomography (PET) scan work in evaluating pyruvate kinase M2 (PKM2) expression in patients with intracranial tumors or recurrent glioblastoma and healthy volunteers.

- **A Study to Assess the Safety and Tolerability of AZD1390 Given With Radiation Therapy in Patients With Brain Cancer**
  - Brief Description: A Phase I clinical trial to test an investigational drug called AZD1390 in combination with radiation therapy for the treatment of brain tumors. This is the first time AZD1390 is being given to patients. This study will test safety, tolerability and PK (how the drug is absorbed, distributed and eliminated) of ascending doses of AZD1390 in combination with distinct regimens of radiation therapy.

- **FET-PET/MRI for Surgical Assessment of Pediatric Brain Tumors**
  - Brief Description: An early Phase 1 clinical trial to determine the percentage of patients whose surgical plan would change with FET-PET/MRI compared to MRI alone, and to determine the percentage of patients who have residual tumor after surgery detected with FET-PET/MRI.

- **Ruxolitinib With Radiation and Temozolomide for Grade III Gliomas and Glioblastoma**
  - Brief Description: A Phase I clinical trial to test how well the drug works, safety and tolerability of an investigational drug called Ruxolitinib in gliomas and glioblastomas, when combined with standard treatment for brain cancer, temozolomide and radiation.
• **Adoptive Cellular Therapy in Pediatric Patients With High-grade Gliomas**
  - **Brief Description:** A Phase I clinical trial that will use a patient's tumor to make a vaccine which aims will stimulate T-cells to kill tumor cells and leave normal cells alone.

• **Brain Stem Gliomas Treated With Adoptive Cellular Therapy During Focal Radiotherapy Recovery Alone or With Dose-intensified Temozolomide (Phase I)**
  - **Brief Description:** A Phase I clinical trial to study to evaluate the immune response of patients who will either receive concurrent temozolomide during radiation and immunotherapy during and after maintenance cycles of dose-intensive temozolomide, or focal radiotherapy alone and immunotherapy without maintenance dose-intensive temozolomide.
  - **LINK:** [https://bit.ly/2LGv0N5](https://bit.ly/2LGv0N5)

• **TAK-580 In Gliomas and Other Tumors**
  - **Brief Description:** A Phase I/II clinical trial studying a drug TAK-580 (MLN2480) as a possible treatment a low-grade glioma that has not responded to other treatments.
  - **LINK:** [https://bit.ly/2y8w67a](https://bit.ly/2y8w67a)

• **Study of AG-120 and AG-881 in Subjects With Low Grade Glioma**
  - **Brief Description:** A Phase I clinical trial to evaluate the suppression of 2-HG (2-hydroxyglutarate) in IDH-1 mutant gliomas in resected tumor tissue following pre-surgical treatment with AG-120 or AG-881.

• **Terameprocol in Treating Patients With Recurrent High Grade Glioma**
  - **Brief Description:** A Phase I trial to study the side effects and best dose of terameprocol in treating patients with high-grade glioma that has come back. Drugs used in chemotherapy, such as terameprocol, work in different ways to stop the growth of tumor cells, either by killing the cells, by stopping them from dividing, or by stopping them from spreading.

• **Olaparib in Treating Patients With Advanced Glioma, Cholangiocarcinoma, or Solid Tumors With IDH1 or IDH2 Mutations**
  - **Brief Description:** A Phase II clinical trial studying how well olaparib works in treating patients with glioma, cholangiocarcinoma, or solid tumors with IDH1 or IDH2 mutations that have spread to other places in the body and usually cannot be cured or controlled with treatment. Olaparib may
stop the growth of tumor cells by blocking some of the enzymes needed for cell growth.

- **Disulfiram and Copper Gluconate With Temozolomide in Unmethylated Glioblastoma Multiforme**
  - *Brief Description:* A Phase II clinical trial to study the impact of DSF + Cu combination when added to standard temozolomide in the treatment of unmethylated GBM patients.

- **Intracerebral EGFR-vIII CAR-T Cells for Recurrent GBM**
  - *Brief Description:* A Phase I clinical trial to designed to determine the maximum tolerated dose (MTD) of a novel, tumor-specific treatment with autologous EGFRvIII-CARs.

- **Safety, Pharmacokinetics and Efficacy of GDC-0084 in Newly-diagnosed Glioblastoma Multiforme**
  - *Brief Description:* A Phase IIa/IIb clinical trial to assess the safety, tolerability, recommended phase 2 dose (RP2D), pharmacokinetics (PK) and clinical activity of GDC-0084 in patients with newly-diagnosed glioblastoma multiforme (GBM) with unmethylated MGMT promoter status as adjuvant therapy following surgical resection and initial chemoradiation with temozolomide (TMZ).

- **Temozolomide, Radiation Therapy, and Tumor Treating Fields Therapy in Treating Participants With Glioblastoma**
  - *Brief Description:* A pilot early Phase I trial to study the side effects of temozolomide, radiation therapy, and tumor treating fields therapy using Novo tumor treatment fields (TTF)-200A device in participants with glioblastoma.

- **Ketogenic Diet in Combination With Standard-of-care Radiation and Temozolomide for Patients With Glioblastoma**
  - *Brief Description:* A Phase I clinical trial to evaluate the safety, nutrition, quality of life, and standard of care tumor assessments over the course of a 16-week ketogenic diet (subject specific as prescribed by RD) while receiving standard of care cancer treatment (radiation + temozolomide).
• **Study Testing The Safety and Efficacy of Adjuvant Temozolomide Plus TTFields (Optune®) Plus Pembrolizumab in Patients With Newly Diagnosed Glioblastoma (2-THE-TOP)**
  o *Brief Description:* A Phase II clinical trial to determine whether the triple combination of pembrolizumab when added to TTFields (Optune®) and adjuvant temozolomide increases progression-free survival (PFS) in patients with newly diagnosed GBM as compared to historical control data.

• **Phase I EGFR BATs in Newly Diagnosed Glioblastoma**
  o *Brief Description:* A Phase I clinical trial using EGFR Bi-armed Activated T-cells (BATs) in combination with standard of care temozolomide (TMZ) and radiation (RT) in patients with glioblastoma (GBM). The purpose of the study is to determine a safe dose of EGFR BATs when given with standard of care therapy and will require a minimum of 3 and a maximum of 18 patients to identify this dose.

• **Tolerability of Cannabis in Patients Receiving Concurrent Chemoradiation for Glioblastoma**
  o *Brief Description:* A Phase I feasibility study to investigate the tolerability of cannabis with concurrent chemoradiation in the treatment of glioblastoma multiforme (GBM). A strain of cannabis provided by The National Institute of Drug Abuse (NIDA) that has a high concentration of cannabidiol (CBD) and a low concentration of THC (relative to average street cannabis) will be tested in order to maximize clinical efficacy while minimizing intoxicating side effects in this medically-ill population.

• **Nivolumab Plus Standard Dose Bevacizumab Versus Nivolumab Plus Low Dose Bevacizumab in GBM**
  o *Brief Description:* A Phase II clinical trial to test the effectiveness (how well the drug works), safety and tolerability of an investigational drug called nivolumab (also known as BMS-936558) in glioblastoma (a malignant tumor, or GBM), when added to bevacizumab.

• **Study of AMG 596 in Patients With EGFRvIII Positive Glioblastoma**
  o *Brief Description:* A Phase 1 study to evaluate safety, tolerability, pharmacokinetics and pharmacodynamics of AMG 596 in subjects with glioblastoma expressing mutant Epidermal Growth Factor Receptor Variant III (EGFRvIII). This is a first in human (FIH), open-label, sequential-dose-escalation study in subjects with EGFRvIII-positive glioblastoma.
- **MDM2 Inhibitor AMG-232 in Treating Patients With Recurrent or Newly Diagnosed Glioblastoma**
  - **Brief Description:** A Phase 0/I trial to study the side effects and best dose of MDM2 inhibitor AMG-232 in treating patients with glioblastoma that is newly diagnosed or has come back. MDM2 inhibitor AMG-232 may stop the growth of tumor cells by blocking some of the enzymes needed for cell growth.
  - **LINK:** [https://bit.ly/2HMr3sI](https://bit.ly/2HMr3sI)

- **Cytokine Microdialysis for Real-Time Immune Monitoring in Glioblastoma Patients Undergoing Checkpoint Blockade**
  - **Brief Description:** A Phase I clinical trial to study how nivolumab affects the brain’s immune system in people who have had glioblastoma brain tumors return, and to investigate how nivolumab and BMS-986016 in combination affect brain tumors.

*This report does not include recently opened Phase III clinical trials, as those will be covered in a separate special report.*