

Brain tumor center launches new clinical trial for recurrent glioblastoma

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A research technician in the pharmacokinetics lab at the Ivy Brain Tumor Center prepares a patient's tissue sample to determine if a new, experimental drug cocktail has penetrated the patient's blood-brain barrier and reached the tumor in sufficient concentrations. Credit: Ivy Brain Tumor Center

The Ivy Brain Tumor Center at Barrow Neurological Institute announced

that patient recruitment has opened for a new Phase 0 clinical trial to evaluate two targeted therapy drugs, abemaciclib and LY3214996. The study will evaluate central nervous system (CNS) penetration in patients with recurrent glioblastoma scheduled for resection. This is the first time a combination of these two drugs will be tested in brain tumor patients.

CDK4/6, or cyclin-dependent kinase 4 and 6, are two proteins found in cells that accelerate growth and division. Abemaciclib, a CDK4/6 inhibitor, has the ability to block these proteins from dividing.

ERK proteins transmit a signal from the surface of a cell to the nucleus that triggers division. LY3214996, an ERK1/2 inhibitor, is a small-molecule drug that can stop the signal and block cancer cell growth.

"The goal of this study is to confirm that both abemaciclib and LY3214996 are uniquely capable of crossing the [blood-brain barrier](#) and effectively hitting their molecular targets in the patient tumor cells. By blocking alternate escape routes, we hope to see this drug cocktail provide survival benefit in patients with the appropriate genetic markers," said Shwetal Mehta, Ph.D., deputy director of the Ivy Brain Tumor Center.

The Ivy Center's innovative Phase 0 [clinical trials](#) program has evolved the traditional Phase 0 design by incorporating a 'trigger' that advances [brain](#) tumor patients into a therapeutic Phase 2 study arm if the drugs are having the desired effects in an individual patient.



In the pursuit of a personalized treatment plan for brain tumor patients, postdoctoral fellows in the Ivy Brain Tumor Center's pharmacodynamics core perform an antibody test to measure a drug's effect in a Phase 0 trial patient's tumor. Credit: Ivy Brain Tumor Center

"Time is the most important commodity for brain [tumor](#) patients. At the Ivy Center, we can identify evidence of drug effects within 10 days of surgery, allowing the patient to either move forward with the experimental [drug cocktail](#) or enroll in another clinical trial without losing time," said Nader Sanai, MD, director of the Ivy Brain Tumor Center.

The Ivy Brain Tumor Center is now screening patients for this study and will enroll up to 50 patients within one year.

Provided by Ivy Brain Tumor Center

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