



NEWS RELEASE

Ivy Brain Tumor Center and BridgeBio Pharma's QED Therapeutics announce dosing of first patient in investigator-initiated phase 0/2 clinical trial of infigratinib in recurrent glioblastoma

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- Precision medicine study designed to confirm drug's ability to cross blood-brain barrier and hit molecular targets in high-grade glioma patients with FGFR genetic alterations
- Patients with a positive PK response will continue on infigratinib after surgery

PHOENIX and SAN FRANCISCO, July 28, 2020 (GLOBE NEWSWIRE) -- [Ivy Brain Tumor Center at Barrow Neurological Institute](#) announced today that the first patient has been dosed in an investigator-initiated Phase 0/2 clinical trial of infigratinib in recurrent high-grade glioma driven by FGFR genetic alterations. Infigratinib is an investigational, orally administered, FGFR1-3 selective tyrosine kinase inhibitor being developed by [BridgeBio Pharma, Inc. \(Nasdaq: BBIO\)](#) affiliate company [QED Therapeutics, Inc.](#)

The investigator-initiated Phase 0/2 trial is designed to confirm drug effects within days of exposure, and only to continue dosing when the drug is active in a patient's own tumor. The primary objective of the Phase 0 arm is to assess how effectively infigratinib can cross the blood-brain barrier – the most significant obstacle to developing new, effective therapies for aggressive brain tumors like glioblastoma. Patients with successful tumor penetration will receive infigratinib long-term in a Phase 2 expansion arm of the trial. The primary endpoint of the expansion phase is progression-free survival rate at six months. The study will also measure how well infigratinib is impacting its molecular target in each patient's tumor.

FGFR (fibroblast growth factor receptor) genetic alterations have been shown to spur growth in malignant tumors.

Five to seven percent of glioblastoma patients' tumors are driven by FGFR signaling. During the trial screening process, the patient's tumor tissue from prior surgery will be tested for the FGFR-TACC3 fusion gene or mutations in FGFR1 and FGFR3 genes. Patients with tumors that have these fusions or mutations are eligible for this study.

"In the preclinical studies, our pharmacokinetics program at the Ivy Brain Tumor Center tested seven FGFR inhibitors for their ability to cross the blood-brain barrier. Infigratinib was one of the most promising agents," said Shwetal Mehta, Ph.D., deputy director of the Ivy Brain Tumor Center.

"Infigratinib was previously tested in an uncontrolled Phase 2 study for recurrent high-grade gliomas," said Nader Sanai, M.D., director of the Ivy Brain Tumor Center. "The results were intriguing, but inconclusive. This Ivy Phase 0/2 trial seeks to provide direct biological evidence of drug effects in individual patients, allowing us to understand which glioblastoma patients may benefit from infigratinib."

"The launch of this investigator-initiated trial is an exciting step in the study of infigratinib for patients with recurrent, high-grade glioma," said Susan Moran, M.D., M.S.C.E., chief medical officer of QED Therapeutics. "We anticipate this study being conducted by the Ivy Center will generate valuable information on the ability of infigratinib to reach brain tumors, which is a critical first step in evaluating whether infigratinib, alone or in combination, could potentially provide a therapeutic option for patients with this dire disease."

For additional information on this Phase 0/2 trial in recurrent high-grade glioma, including eligibility criteria, visit www.clinicaltrials.gov/ct2/show/NCT04424966.

About Ivy Brain Tumor Center

Ivy Brain Tumor Center at the Barrow Neurological Institute in Phoenix, AZ is a non-profit translational research program that employs a bold, early-phase clinical trials strategy to identify new treatments for aggressive brain tumors, including glioblastoma. The Ivy Center's Phase 0 clinical trials program is the largest of its kind in the world and enables personalized care in a fraction of the time and cost associated with traditional drug development. Unlike conventional clinical trials focusing on single drugs, its accelerated trials program tests therapeutic combinations matched to individual patients. Learn more at IvyBrainTumorCenter.org. Follow the Ivy Brain Tumor Center on [Facebook](#), [Instagram](#), [Twitter](#) and [LinkedIn](#).

About QED Therapeutics, Inc.

QED Therapeutics, an affiliate of BridgeBio Pharma, Inc. is a biotechnology company focused on precision medicine for FGFR-driven diseases. Our lead investigational candidate is infigratinib (BGJ398), an orally administered, FGFR1-3 selective tyrosine kinase inhibitor that has shown activity that we believe to be meaningful in clinical measures,

such as overall response rate, in patients with chemotherapy-refractory cholangiocarcinoma with FGFR2 fusions and advanced urothelial carcinoma with FGFR3 genomic alterations. QED intends to submit a New Drug Application (NDA) with the United States Food and Drug Administration for second and later-line cholangiocarcinoma in 2020. QED Therapeutics is also evaluating infigratinib in clinical studies for the treatment of achondroplasia. We plan to conduct further clinical trials to evaluate the potential for infigratinib to treat patients with other FGFR-driven tumor types and rare disorders.

For more information on QED Therapeutics, please visit the Company's website at www.qedtx.com.

About BridgeBio Pharma, Inc.

BridgeBio is a team of experienced drug discoverers, developers and innovators working to create life-altering medicines that target well-characterized genetic diseases at their source. BridgeBio was founded in 2015 to identify and advance transformative medicines to treat patients who suffer from Mendelian diseases, which are diseases that arise from defects in a single gene, and cancers with clear genetic drivers. BridgeBio's pipeline of over 20 development programs includes product candidates ranging from early discovery to late-stage development. For more information visit bridgebio.com

BridgeBio Pharma Forward Looking Statements

This press release contains forward-looking statements. All statements contained herein other than statements of historical fact constitute forward-looking statements, including statements relating to expectations, plans, and prospects regarding QED Therapeutics' clinical development plans, clinical trial results, timing, completion and outcomes of clinical trials, including this investigator-initiated trial, the competitive environment, the success of QED Therapeutics' collaboration with the Ivy Brain Tumor Center and its impact on QED Therapeutics' clinical development strategy, and the clinical and therapeutic potential of infigratinib. These forward-looking statements are subject to a number of risks, uncertainties and assumptions, including, but not limited to, QED Therapeutics' ability to initiate and continue its planned clinical trials of infigratinib, its ability to advance infigratinib in clinical development, the timing and success of any such continued clinical development, and the Ivy Brain Tumor Center's ability to initiate and enroll its investigator-initiated clinical trial of infigratinib and the nature of QED's interactions with regulatory authorities. Moreover, QED Therapeutics operates in a very competitive and rapidly changing environment in which new risks emerge from time to time. These forward-looking statements are based upon the current expectations and beliefs of QED Therapeutics' management as of the date of this release and are subject to certain risks and uncertainties that could cause actual results to differ materially from those described in the forward-looking statements. All forward-looking statements in this press release are based on information available to QED Therapeutics as of the date hereof, and QED Therapeutics disclaims any obligation to update these forward-looking statements.

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