



NEWS RELEASE

# bridgebio pharma's qed therapeutics announces dosing of first patients in phase 3 and phase 2 clinical trials of infigratinib in tumors with fgfr genetic alterations

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PROOF 302 Trial Enrolling Subjects with Invasive Urothelial Carcinoma with Susceptible FGFR3 Genetic Alterations

Ohio State University-Led Trial to Study Infigratinib for Treatment of Patients with Advanced or Metastatic Solid Tumors with FGFR Genetic Alterations

SAN FRANCISCO, March 12, 2020 (GLOBE NEWSWIRE) -- BridgeBio Pharma, Inc. (Nasdaq: BBIO) affiliate company QED Therapeutics announced today that patients have been dosed in separate Phase 3 and Phase 2 clinical trials of infigratinib in cancer indications.

The Phase 3 PROOF 302 trial sponsored by QED is studying infigratinib for the adjuvant (post-surgery) treatment of invasive urothelial carcinoma. A second, investigator-initiated trial, led by Sameek Roychowdhury, M.D., Ph.D., of The Ohio State University (OSU) Comprehensive Cancer Center, is studying infigratinib for the treatment of advanced and metastatic solid tumors with confirmed FGFR gene fusions/translocations or other FGFR alterations.

In the PROOF 302 trial, investigators are enrolling subjects with invasive urothelial cancer harboring susceptible FGFR3 genetic alterations who are at high risk of recurrence following surgical resection. Subjects will be randomized (1:1) to receive once daily oral infigratinib or placebo. The primary outcome is disease-free survival, and secondary outcomes include metastasis-free survival, overall survival, and safety and tolerability measures.

“Many patients with invasive urothelial carcinoma will have their cancer recur within two years after surgery,” said PROOF 302 trial lead Sumanta Pal, M.D., professor of medical oncology and therapeutics research at City of Hope Comprehensive Cancer Center. “Correspondingly, I believe there are many patients who could benefit from an oral, post-surgery treatment option that targets FGFR3 alterations, the genetic driver of many urothelial carcinomas.”

The Phase 2 study at OSU and selected sites within the Oncology Research Information Exchange Network (ORIEN) will evaluate the efficacy of infigratinib in patients who have advanced or metastatic solid tumors that are positive for FGFR1-3 gene fusions/translocations or other FGFR alterations. The open-label study will assess overall response rate as the primary outcome. Secondary outcomes include progression-free survival, best overall response, disease control rate, overall survival and measures of safety and tolerability.

“Increasingly, oncologists are learning to classify their patients’ cancers based on genetic mutations, going beyond the origin of the tumor,” noted Dr. Roychowdhury. “Given the activity we have seen with infigratinib in FGFR2-fusion-driven bile duct cancers and FGFR3-altered urothelial carcinoma, our hope is that infigratinib will demonstrate similar activity in additional cancers that appear to be driven by alterations in FGFR. There appear to be multiple FGFR alterations that can drive cancer growth—and we hope to see these patients benefit too.”

For additional information on the PROOF 302 trial, including eligibility, patients should ask their physician, visit [clinicaltrials.gov](https://clinicaltrials.gov), or email [PROOF302@QEDtx.com](mailto:PROOF302@QEDtx.com).

For additional information on the Phase 2 trial in metastatic solid tumors with FGFR gene alterations, including eligibility, patients should ask their physician, visit [clinicaltrials.gov](https://clinicaltrials.gov), or email [OSUCCCClinicaltrials@osumc.edu](mailto:OSUCCCClinicaltrials@osumc.edu).

#### About QED Therapeutics

QED Therapeutics, an affiliate of BridgeBio Pharma, 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 (FDA) for second and later-line cholangiocarcinoma in 2020. QED Therapeutics is also evaluating infigratinib in preclinical 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 [qedtx.com](https://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](http://bridgebio.com).

#### BridgeBio Pharma Forward-Looking Statements

This press release contains forward-looking statements. Statements we make in this press release may include statements that are not historical facts and are considered forward-looking within the meaning of Section 27A of the Securities Act of 1933, as amended (the "Securities Act"), and Section 21E of the Securities Exchange Act of 1934, as amended (the "Exchange Act"), which are usually identified by the use of words such as "anticipates," "believes," "estimates," "expects," "intends," "may," "plans," "projects," "seeks," "should," "will," and variations of such words or similar expressions. We intend these forward-looking statements to be covered by the safe harbor provisions for forward-looking statements contained in Section 27A of the Securities Act and Section 21E of the Exchange Act and are making this statement for purposes of complying with those safe harbor provisions. These forward-looking statements, including statements relating to expectations, plans, and prospects regarding QED Therapeutics' regulatory approval process, clinical trial designs, clinical development plans, clinical trial results, timing and completion of clinical trials, clinical and therapeutic potential of infigratinib, reflect our current views about our plans, intentions, expectations, strategies and prospects, which are based on the information currently available to us and on assumptions we have made. Although we believe that our plans, intentions, expectations, strategies and prospects as reflected in or suggested by those forward-looking statements are reasonable, we can give no assurance that the plans, intentions, expectations or strategies will be attained or achieved. Furthermore, actual results may differ materially from those described in the forward-looking statements and will be affected by a number of risks, uncertainties and assumptions, including, but not limited to, QED Therapeutics' ability to initiate and continue its ongoing and planned clinical trials of infigratinib, the availability of data from these trials, its ability to advance infigratinib in clinical development according to its plans, and the timing of these events, as well as those risks set forth in the Risk Factors section of BridgeBio Pharma, Inc.'s most recent Annual Report on Form 10-K and our other SEC filings. Moreover, QED Therapeutics operates in a very competitive and rapidly changing environment in which new risks emerge from time to time. Except as required by applicable law, we assume no obligation to update publicly any forward-looking statements, whether as a result of new information, future events or otherwise.

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