NEWS RELEASE

bridgebio pharma's qed therapeutics receives fast track designation for infigratinib in adults with first-line advanced or metastatic cholangiocarcinoma and orphan drug designation for infigratinib for treatment of cholangiocarcinoma

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The PROOF trial, a Phase 3 trial of infigratinib in first-line cholangiocarcinoma, is currently enrolling

SAN FRANCISCO, Jan. 06, 2020 (GLOBE NEWSWIRE) -- BridgeBio Pharma, Inc. (Nasdaq: BBIO) subsidiary QED Therapeutics announced today that it has secured both Fast Track Designation in adults with first-line advanced or metastatic cholangiocarcinoma and Orphan Drug Designation for infigratinib for treatment of cholangiocarcinoma. In addition, the company announced that enrollment is ongoing and patient dosing has started in the PROOF trial, a Phase 3 clinical trial evaluating oral infigratinib, an investigational drug, in adults for first-line treatment of advanced cholangiocarcinoma with FGFR2 (fibroblast growth factor receptor 2) gene fusions or translocations.

Cholangiocarcinoma, a cancer of the bile ducts of the liver, is a serious and often fatal disease which affects approximately 20,000 people in the United States and European Union each year. FGFR2 genetic aberrations are present in approximately 15% to 20% of people who have this disease. Currently, treatment options are limited, and the 5-year survival rate is only 9%.[1]

Infigratinib received Fast Track Designation for first-line treatment of adult patients with unresectable locally advanced or metastatic cholangiocarcinoma with FGFR2 gene fusions or translocations.

"We believe that Fast Track and Orphan Drug Designations for infigratinib for the treatment of cholangiocarcinoma

underscores the need for new, targeted treatments for genetically-driven subsets of this cancer, particularly for adults with first-line advanced or metastatic cholangiocarcinoma," said Susan Moran, MD, MSCE, chief medical officer for QED. "Fast Track Designation will enhance our interaction with the FDA on our first-line advanced or metastatic cholangiocarcinoma program and may help us get this medicine to patients more quickly."

The PROOF trial will enroll approximately 384 patients with first-line cholangiocarcinoma with FGFR2 fusions or translocations, as determined by molecular profiling. The primary endpoint is progression-free survival compared to standard of care chemotherapy (gemcitabine and cisplatin). Patients will be randomized 2:1 to infigratinib versus standard of care.

"Importantly, in this trial, patients who are assigned to receive standard of care will be allowed to cross over and receive infigratinib if they do not respond to chemotherapy," said Stacie Lindsey, president of the Cholangiocarcinoma Foundation. "Having a crossover option is very significant to patients and including it in the design of this trial demonstrates that QED is listening to them."

For additional information on the PROOF trial, including eligibility, patients should ask their physician, visit clinicaltrials.gov, or email **PROOF301@QEDtx.com**

For more information on molecular profiling, patients can find resources from the Cholangiocarcinoma Foundation at **https://cholangiocarcinoma.org/mutationsmatter**.

About Orphan Drug Designation

Under the FDA's Orphan Drug Designation program, orphan drug designation is granted by the FDA to drugs or biologics intended to treat rare diseases or conditions. The designation allows the drug developer to be eligible for a seven-year period of U.S. marketing exclusivity upon approval of the drug, if the drug receives the first FDA approval for the rare disease or condition, as well as tax credits for clinical research costs, the ability to apply for annual grant funding, clinical trial design assistance, and the waiver of Prescription Drug User Fee Act (PDUFA) filing fees.

About U.S. FDA's Fast Track Designation Program

The FDA's Fast Track program was established to facilitate the development and expedite the review of drugs with the potential to treat serious conditions and address an unmet medical need. Companies that receive Fast Track designation are provided the opportunity for more frequent interactions with FDA during clinical development and are eligible for accelerated approval and/or priority review, if relevant criteria are met. Additionally, companies that receive Fast Track designation are allowed to submit completed sections of their New Drug Application (NDA) or

Biologics License Application (BLA) for the drug on a rolling basis, resulting in the potential for an expedited FDA review process.

About QED Therapeutics

QED Therapeutics, a subsidiary 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. In addition to the first-line cholangiocarcinoma program and the Phase 3 PROOF trial, QED has also studied infigratinib in a Phase 2, open-label study in second and later-line cholangiocarcinoma and intends to pursue an NDA filing for this indication 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 **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 15 development programs includes product candidates ranging from early discovery to late-stage development.

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, the availability of marketing exclusivity and other benefits under the FDA's Orphan Drug Designation program, and the availability of accelerated approval or priority review under the FDA's Fast Track program, 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 Quarterly Report on Form 10-Q 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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[1]Dhanasekaran, R., Hemming, A. W., Zendejas, I., George, T., Nelson, D. R., Soldevila-Pico, C., Firpi, R. J., Morelli, G., Clark, V., Cabrera, R. "Treatment outcomes and prognostic factors of intrahepatic cholangiocarcinoma". Oncology Reports 29.4 (2013): 1259-1267.

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