



NEWS RELEASE

## bridgebio pharma's qed therapeutics presents data on infigratinib in cholangiocarcinoma and urothelial carcinoma at the american society of clinical oncology 2020 virtual scientific program

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SAN FRANCISCO, May 29, 2020 (GLOBE NEWSWIRE) -- BridgeBio Pharma, Inc. (Nasdaq: BBIO) affiliate QED Therapeutics announced today that it will present data at the American Society of Clinical Oncology 2020 Virtual Scientific Program showing clinical advancement for infigratinib, QED's oral FGFR1-3 inhibitor, in both urothelial carcinoma and cholangiocarcinoma (CCA).

Title: Infigratinib (BGJ398) in advanced/unresectable or metastatic urothelial carcinoma demonstrates consistent treatment response in both first-line and later-line treatment settings

### **Abstract: 5038**

Presenter: Yung Lyou, City of Hope Comprehensive Cancer Center

An analysis of response rates in patients with advanced/unresectable or metastatic urothelial carcinoma based on the amount of prior lines of treatment showed consistent response to infigratinib. The objective response rate (ORR) for all patients (n=67) was 25% (95% CI 15.5-37.5), while the ORR for patients receiving infigratinib as first-line treatment (n=13) saw a response rate of 31% (95% CI 9.1-61.4) compared to 24% (95% CI 13.5-37.6) for patients receiving infigratinib as a second-line or later treatment (n=54). All eight patients in the study with upper tract urothelial carcinoma (UTUC) received infigratinib as second-line or later therapy. The response rates were higher

for patients with UTUC, with an ORR of 50% (95% CI 15.7–84.3) and a disease control rate of 100%. In the study, treatment emergent adverse events occurring in >30% of patients were: hyperphosphatemia (46%), elevated creatinine (42%), fatigue (37%), constipation (37%), anemia (36%), decreased appetite (33%), dry mouth (31%), and alopecia (31%).

“These findings support the design of the ongoing, placebo-controlled PROOF 302 study to evaluate the efficacy of infigratinib in adjuvant urothelial carcinoma,” said author and PROOF 302 trial lead Sumanta Pal, MD, professor of medical oncology and therapeutics research at City of Hope Comprehensive Cancer Center. “The results in upper tract urothelial cancer (UTUC) build upon earlier research that the disease has a different genetic profile than urothelial carcinoma of the bladder, particularly with respect to FGFR3 alterations, and warrants further investigation in an even earlier setting.”

Title: A retrospective analysis of post second-line chemotherapy treatment outcomes for patients with advanced or metastatic cholangiocarcinoma and FGFR2 fusions

#### **Abstract: 4591**

Presenter: Milind M. Javle, MD Anderson Cancer Center

In a retrospective analysis of a subset of a single-arm Phase 2 study of infigratinib (n=37), outcomes from patients with FGFR-fusion-positive bile duct cancer receiving infigratinib as third- and later-line therapy were compared with the tumor response when those same patients received second-line therapy with chemotherapy. Treatment with infigratinib resulted in progression free survival (PFS) improvements. The median PFS was 6.8 months (95% CI 3.9-7.8 months) for third- and later-line infigratinib treatment compared to 4.6 months (95% CI 2.7-7.2 months) for second-line chemotherapy.

“Through this retrospective analysis, we can see that infigratinib may have potential for patients whose tumors progress after second-line chemotherapy,” said Susan Moran, MD, MSCE, chief medical officer for QED. “These data support continued investigation of infigratinib in patients with FGFR-driven cholangiocarcinoma.”

#### 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 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 [www.qedtx.com](http://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](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, the timing of the submission of a New Drug Application (NDA) for second- and later-line cholangiocarcinoma, clinical trial designs, including the design of the ongoing, placebo-controlled PROOF 302 study, clinical development plans, clinical trial results, timing and completion of clinical trials, clinical and therapeutic potential of infigratinib, including for patients whose tumors progress after second-line chemotherapy, 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, past data not being indicative of future data, its ability to advance infigratinib in clinical development according to its plans, and the timing of these events, including the planned NDA submission in 2020, as well as those risks set forth in the Risk Factors section of BridgeBio Pharma's most recent Quarterly Report on Form 10-Q and BridgeBio Pharma's 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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