



NEWS RELEASE

bridgebio pharma and affiliate qed therapeutics announce fda acceptance of new drug application for infigratinib for the treatment of cholangiocarcinoma

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- Application accepted under Priority Review designation
- Application accepted into Real Time Oncology Review (RTOR) pilot program
 - This is BridgeBio's second NDA acceptance
- Application will also be submitted for review in Australia and Canada under Project Orbis

PALO ALTO, Calif., Dec. 01, 2020 (GLOBE NEWSWIRE) -- BridgeBio Pharma, Inc. (NASDAQ: BBIO), a clinical-stage biopharmaceutical company founded to discover, create, test and deliver meaningful medicines for patients with genetic diseases and cancers with clear genetic drivers, and affiliate QED Therapeutics today announced that the U.S. Food and Drug Administration (FDA) has accepted their New Drug Application (NDA) for infigratinib, an oral FGFR1-3 selective inhibitor, for individuals with cholangiocarcinoma, or cancer of the bile ducts.

The NDA has been granted Priority Review designation and is being reviewed under the Real-Time Oncology Review (RTOR) pilot program, an initiative of the FDA's Oncology Center of Excellence designed to expedite the delivery of safe and effective cancer treatments to patients. Additionally, BridgeBio will submit for review in Australia and Canada under Project Orbis, an initiative of the FDA's Oncology Center of Excellence that allows for concurrent submission and review of oncology drugs among participating international regulatory agencies.

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 five-year survival rate is only 9%.

“We want to thank the patients, families, scientists, physicians and all others involved who helped us move this NDA forward. At BridgeBio we believe that every minute counts for patients and their families, and we are eager to help as many people suffering from cholangiocarcinoma as possible – as quickly as possible,” said BridgeBio CEO and Founder Neil Kumar, Ph.D.

This is BridgeBio's second NDA acceptance following the acceptance of its NDA for fosdenopterin in molybdenum cofactor deficiency (MoCD) Type A in September 2020.

About Infigratinib

Infigratinib is an orally administered, ATP-competitive, FGFR1-3 tyrosine kinase inhibitor in development for the treatment of individuals with FGFR-driven conditions, including cholangiocarcinoma (bile duct cancer), urothelial carcinoma (bladder cancer) and achondroplasia, a bone growth condition in children.

About QED Therapeutics

QED Therapeutics, an affiliate of BridgeBio Pharma, is a biotechnology company focused on precision medicine for FGFR-driven diseases. Its lead investigational candidate is infigratinib (BGJ398), an orally administered, FGFR1-3 selective tyrosine kinase inhibitor that has shown activity that it believes, based on published data to date, 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 submitted 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. QED plans 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, please visit www.qedtx.com.

About BridgeBio Pharma, Inc.

BridgeBio is a team of experienced drug discoverers, developers and innovators working to discover, create, test and deliver 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. 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 QED's clinical development plans, clinical trial results, timing and completion of clinical trials and regulatory submissions, competitive environment and 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's ability to continue its planned clinical development and regulatory submissions for infigratinib and the timing and success of any such continued clinical development and planned regulatory submissions, as well as those risks set forth in the Risk Factors section of BridgeBio Pharma's most recent Annual Report on Form 10-K, Quarterly Report on Form 10-Q and BridgeBio Pharma's other SEC filings. Moreover, BridgeBio Pharma 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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