NEWS RELEASE

helsinn group and bridgebio pharma's affiliate qed therapeutics announce health canada conditional approval of truseltiq™ (infigratinib) for patients with cholangiocarcinoma

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- Health Canada Issues Conditional Approval of TRUSELTIQ under Project Orbis (September 27th, 2021)

LUGANO, Switzerland, and PALO ALTO, CA, September 29, 2021 – Helsinn Group and BridgeBio Pharma, Inc. (Nasdaq: BBIO), through its affiliate QED Therapeutics, Inc., today announced that Health Canada has approved TRUSELTIQ™ (infigratinib), a small molecule kinase inhibitor that targets fibroblast growth factor receptor (FGFR), under the Notice of Compliance with Conditions (NOC/c) policy, for the treatment of adults with previously treated, unresectable locally advanced or metastatic cholangiocarcinoma (CCA) with a FGFR2 fusion or other rearrangement.

An NOC/c is a form of market approval granted to a product on the basis of promising evidence of clinical effectiveness following review of the submission by Health Canada. Products authorized under Health Canada's NOC/c policy are intended for the treatment, prevention or diagnosis of a serious, life-threatening or severely debilitating illness. They have demonstrated promising benefit, are of high quality and possess an acceptable safety profile based on a benefit/risk assessment. In addition, they either respond to a serious unmet medical need in Canada or have demonstrated a significant improvement in the benefit/risk profile over existing therapies. Health Canada has provided access to this product on the condition that sponsors carry out additional clinical trials to verify the anticipated benefit within an agreed upon time frame.

"This is an important next step in growing TRUSELTIQ's global reach. We are pleased to have achieved this

milestone for patients with previously-treated locally advanced or metastatic cholangiocarcinoma harboring an FGFR2 fusion or other rearrangement," said Riccardo Braglia, Helsinn Group Vice Chairman and CEO. "The conditional approvals from the U.S. FDA and Health Canada mark the beginning of our journey delivering this medicine to patients in need. We look forward to working to enter further markets in the months and years ahead and working closely with BridgeBio as we make strides to reach patients."

"We are grateful for our first international approval and the opportunity to reach patients outside the United States who are searching for options to treat FGFR2-fusion-driven cholangiocarcinoma. Helsinn has an impressive track record of advancing and commercializing oncology therapies around the globe and we partnered with them earlier this year in the hope of reaching as many patients with FGFR-driven cancers as possible," said BridgeBio CEO and Founder Neil Kumar, Ph.D. "We believe infigratinib may be able to treat other FGFR-driven conditions and we will continue to evaluate its safety and efficacy in urothelial carcinoma and other areas of unmet need."

Under Project Orbis, an initiative of the FDA, Oncology Center of Excellence that allows for concurrent submission and review of oncology drugs among participating international regulatory agencies, TRUSELTIQ received accelerated approval from the U.S. Food and Drug Administration (FDA) in May 2021. An additional marketing application for infigratinib is currently under review in Australia.

Helsinn Group has exclusive commercial rights for TRUSELTIQ in Canada with BridgeBio eligible for tiered royalties as a percentage of net sales as part of the global collaboration and license agreement entered into between the two companies in March 2021.

As part of this agreement, BridgeBio and Helsinn Group's affiliate, Helsinn Therapeutics U.S., Inc., are jointly responsible for commercialization activities for TRUSELTIQ in the U.S. and will share U.S. profits and losses on an equal basis. Helsinn Group will have exclusive commercialization rights on infigratinib outside of the U.S., excluding China, Hong Kong and Macau. BridgeBio will be eligible for tiered royalties as a percentage of adjusted net sales, and payments totaling up to approximately $2.45 billion USD in the aggregate. Helsinn Group will fund the majority of ongoing and future research and development related to infigratinib in oncology. BridgeBio previously entered a strategic collaboration with LianBio for development and commercialization of infigratinib in oncology indications in China, Hong Kong and Macau.

About TRUSELTIQ™ (infigratinib)

TRUSELTIQ (infigratinib) is a small molecule kinase inhibitor that targets FGFR, which obtained accelerated approval by FDA and was conditionally approved by Health Canada for the treatment of adults with previously treated, unresectable locally advanced or metastatic CCA with a FGFR2 fusion or other rearrangement.

Prior to initiation of TRUSELTIQ therapy, FGFR2 fusion or rearrangement should be established using a validated test.

Clinical effectiveness of TRUSELTIQ is based on overall response rate (ORR) and duration of response (DoR) from a single-arm Phase 2 trial in patients with specific FGFR2 fusion or other rearrangements.

Infigratinib is not FDA- or Health Canada-approved for any other indication in the United States and Canada, and is not approved for use by any other health authority.

About Cholangiocarcinoma (CCA)

CCA represents an aggressive group of malignancies that form in the bile ducts. The incidence of this serious and fatal disease varies considerably worldwide. As the disease is usually asymptomatic at early-stages, CCA typically presents at diagnosis as locally advanced or metastatic disease with a poor prognosis. In this respect, the five-year survival rate for patients affected by metastatic CCA is 2%. Depending on the anatomical site of origin, CCAs are classified into two subtypes: intrahepatic (iCCA – 10% of total) and extrahepatic (eCCA – 90% of total) CCA. Approximately 10% to 16% of iCCA harbor FGFR2 genetic alterations.[1, 2, 3]

About Helsinn Group

Helsinn is a Swiss Biopharmaceutical Group with an innovative R&D pipeline in cancer supportive care and oncology therapeutics, strategically investing in a fully integrated targeted therapy structure to develop, manufacture and commercialize small molecules in precision medicine with higher market potential, thanks to a consolidated track record, a solid revenue stream in B2B and strong cash flow and cash position.

Helsinn is building market differentiation in B2C in the U.S. and China and is owned by a third-generation healthcare entrepreneurial family.

Since 1976, Helsinn has been improving the lives of patients, guided by core family values of respect, integrity and quality, through a unique integrated licensing business model, and by collaborating with success in about 190 countries with long-standing partners who share our values.

The Group's pharmaceutical business (Helsinn Healthcare S.A.) is headquartered in Lugano, Switzerland with operating subsidiaries in the U.S. (Helsinn Therapeutics (U.S.) Inc.) and China (Helsinn Pharmaceuticals (Beijing) Co., Ltd.) which market products directly in these countries. The company has additional operating subsidiaries in Switzerland (Helsinn Advanced Synthesis S.A., an active pharmaceutical ingredient manufacturer) and Ireland (Helsinn Birex Pharmaceuticals Ltd., a drug product manufacturer).

Helsinn Group plays an active and central role in promoting social transformation in favor of people and the environment. Corporate social responsibility is at the heart of everything we do, which is reinforced in the company's strategic plan by a commitment to sustainable growth.

For more information, please visit **helsinn.com** and follow us on **Twitter**, **LinkedIn** and **Vimeo**.

About BridgeBio Pharma, Inc.

BridgeBio Pharma (BridgeBio) is a biopharmaceutical company founded to discover, create, test and deliver transformative medicines to treat patients who suffer from genetic diseases and cancers with clear genetic drivers. BridgeBio's pipeline of over 30 development programs ranges from early science to advanced clinical trials and its commercial organization is focused on delivering the company's first two approved therapies. BridgeBio was founded in 2015 and its team of experienced drug discoverers, developers and innovators are committed to applying advances in genetic medicine to help patients as quickly as possible. For more information visit **bridgebio.com** and follow us on **LinkedIn** and **Twitter**.

BridgeBio Pharma, Inc. 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: the co-commercialization by QED Therapeutics, Inc. (QED) and partner Helsinn Group (Helsinn) of TRUSELTIQ™ (infigratinib) for the treatment of patients with previously-treated locally advanced or metastatic cholangiocarcinoma (CCA) harboring an FGFR2 fusion or rearrangement in Canada; Helsinn's exclusive commercialization rights outside of the United States and in Canada, excluding China, Hong Kong and Macau; the potential for infigratinib to treat a range of FGFR-driven conditions, including other cancers; the safety profile of TRUSELTIQ for the treatment of patients with FGFR2 fusion driven CCA, including the most common adverse reactions and drug interactions; plans for the supply, manufacturing and distribution of TRUSELTIQ; the incidence and survival rate of CCA; the current -approved TRUSELTIQ dosage and administration; the planned approval of TRUSELTIQ by foreign regulatory authorities and the necessary clinical trial results, and timing and completion of regulatory submissions related thereto; and the competitive environment and clinical and

therapeutic potential of TRUSELTIQ; 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 variety of risks and factors that are beyond our control including, without limitation: the safety, tolerability and efficacy profile of TRUSELTIQ observed to date may change adversely in ongoing analyses of trial data or subsequent to commercialization; despite having ongoing interactions with the FDA, Health Canada or other regulatory agencies, the FDA, Health Canada or such other regulatory agencies may not agree with QED's regulatory approval strategies, components of QED's filings, such as clinical trial designs, conduct and methodologies, or the sufficiency of data; the fact that accelerated approval of TRUSELTIQ was granted by Health Canada based on overall response rate and duration of response, and continued approval for this indication may be contingent upon verification of clinical benefit in confirmatory trial(s); QED and/or Helsinn may encounter delays in meeting manufacturing or supply timelines or disruptions in their distribution plans for TRUSELTIQ; whether and when any regulatory submissions may be filed in various foreign jurisdictions and ultimately approved by foreign regulatory authorities; the continuing success of the BridgeBio and Helsinn global collaboration and licensing agreement and the co-commercialization efforts thereunder; Helsinn's ability to commercialize TRUSELTIQ outside of the United States and in Canada, excluding China, Hong Kong and Macau; and potential adverse impacts due to the global COVID-19 pandemic such as delays in regulatory review, manufacturing and clinical trials, supply chain interruptions, adverse effects on healthcare systems and disruption of the global economy; as well as those set forth in the Risk Factors section of BridgeBio Pharma, Inc.'s most recent Annual Report on Form 10-K filed with the U.S. Securities and Exchange Commission (SEC) and in subsequent SEC filings, which are available on the SEC's website at **www.sec.gov**. Except as required by law, each of BridgeBio and QED disclaims any intention or responsibility for updating or revising any forward-looking statements contained in this press release in the event of new information, future developments or otherwise. Moreover, BridgeBio and QED operate in a very competitive environment in which new risks emerge from time to time. These forward-looking statements are based on each of BridgeBio's and QED's current expectations, and speak only as of the date hereof.

References

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