

BridgeBio Pharma’s Affiliate QED Therapeutics and Helsinn Group Announce Strategic Collaboration to Co-Develop and Commercialize Infigratinib in Oncology

- *BridgeBio, through its Affiliate QED (“BridgeBio”), and Helsinn to co-commercialize infigratinib for oncology and all other indications other than skeletal dysplasia indications in the U.S. and equally share profits*
- *Helsinn Group will have an exclusive license to co-develop, manufacture and commercialize infigratinib in such indications outside of the U.S., excluding China, Hong Kong and Macau*
- *BridgeBio will be eligible to receive more than \$2 billion USD in upfront, regulatory and commercial milestone payments*
- *BridgeBio retains full rights to infigratinib for use in skeletal dysplasias, including for achondroplasia*

PALO ALTO, Calif. and LUGANO, Switzerland – March 31, 2021 – BridgeBio Pharma, Inc. (Nasdaq: BBIO), through its affiliate QED Therapeutics, Inc., and Helsinn Group today announced a global collaboration and licensing agreement (the “Agreement”) to further develop and commercialize QED Therapeutics’ FGFR1-3 inhibitor, infigratinib, in oncology and all other indications except for skeletal dysplasias (including achondroplasia). Completion of the Agreement is subject to regulatory review and customary closing conditions, which are expected to occur in the second quarter of 2021.

Infigratinib is an orally administered, ATP-competitive, tyrosine kinase inhibitor that is designed to inhibit FGFR, and being investigated for treatment of individuals with FGFR-driven conditions, including cholangiocarcinoma (bile duct cancer), urothelial carcinoma (urinary tract and bladder cancer), and other FGFR-driven cancers.

Under the terms of the Agreement, BridgeBio will retain all rights to infigratinib in skeletal dysplasia, including achondroplasia. Subject to U.S. Food and Drug Administration (“FDA”) approval, QED and Helsinn will co-commercialize infigratinib in oncology indications in the U.S.



and will share profits and losses on a 50:50 basis. Helsinn will have exclusive commercialization rights and lead commercialization for infigratinib in non-skeletal dysplasia indications outside of the U.S., excluding China, Hong Kong and Macau, which are covered by BridgeBio's strategic development and commercialization collaboration with LianBio. Under the Agreement, BridgeBio will be eligible to receive more than \$2 billion in upfront, regulatory and commercial milestones, as well as tiered royalties on adjusted net sales from Helsinn Group.

"We are privileged to partner with Helsinn as we strive to unlock the full potential of infigratinib for patients with FGFR-driven cancers," **said BridgeBio CEO and founder, Neil Kumar, Ph.D.** "Helsinn has an impressive track record of advancing and commercializing oncology therapies around the globe. Our hope is that partnering with Helsinn will significantly strengthen our anticipated upcoming launch of infigratinib and our ongoing research into infigratinib's potential across other cancer indications."

Riccardo Braglia, Helsinn Group Vice Chairman and CEO, commented, "As a leader in oncology therapeutics and supportive care, Helsinn is always looking to partner with high quality companies. The combination of BridgeBio and its lead oncology product candidate, infigratinib, fall into the strategic sweet spot of a quality company and product with which we look to work. We are highly excited by the potential positive impact this collaboration can deliver for patients around the world."

BridgeBio and Helsinn Group intend to pursue an ambitious co-development plan in oncology indications, including clinical investigation underway in first-line cholangiocarcinoma and adjuvant urothelial cancer. This plan will be underpinned by close collaboration among the parties, with the aim of developing new treatments for patients with FGFR-driven cancers. As infigratinib heads toward potential approval and commercialization in a range of oncology indications, Helsinn's unique integrated licensing business model will enable its distribution to reach patients globally.

The FDA has accepted the New Drug Application ("NDA") for infigratinib for patients with previously-treated advanced cholangiocarcinoma ("CCA") harboring an FGFR2 gene fusion or rearrangement. 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, infigratinib is currently under 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.

About QED Therapeutics, Inc.

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. For more information, please visit www.qedtx.com.

About BridgeBio Pharma, Inc.

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 approved therapy. 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.



About Helsinn Group

Helsinn is a privately-owned Swiss Pharma Company which, since 1976, has been improving the lives of patients, guided by core family values of respect, integrity and quality. The Group has an extensive portfolio of marketed innovative cancer and rare disease therapies, a robust drug development pipeline and ambitions to further accelerate its growth through in-licensing and acquisitions to address unmet medical needs. Helsinn operates a unique integrated licensing business model, achieving success with long-standing partners in 190 countries, who share our values. The Group's pharmaceutical business (Helsinn Healthcare) is headquartered in Lugano, Switzerland with operating subsidiaries in the U.S. (Helsinn Therapeutics US) and China (Helsinn Pharmaceuticals China) which market the Group's products directly in these countries. The Group has additional operating subsidiaries in Switzerland (Helsinn Advanced Synthesis, an active pharmaceutical ingredient manufacturer) and Ireland (Helsinn Birex Pharmaceuticals, a drug product manufacturer). 3B Future Health Fund (formerly known as Helsinn Investment Fund) was created to enhance the future of healthcare by providing funding and strategic support to innovative companies.

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 www.helsinn.com and follow us on [Twitter](#), [LinkedIn](#) and [Vimeo](#).

BridgeBio Pharma Forward-Looking Statements

This press release contains forward-looking statements 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 include statements relating to expectations, plans and prospects regarding clinical development plans, clinical and therapeutic potential, regulatory status and commercial strategy for infigratinib, including, but not limited to: the successful completion of the global collaboration and licensing agreement between QED Therapeutics, Inc. and Helsinn Group (the Agreement), including regulatory approval of our Hart-Scott-Rodino filing, and the timing thereof; despite having ongoing interactions with the U.S. Food and Drug Administration (FDA) or other regulatory agencies, the FDA or such other regulatory agencies may not agree with BridgeBio's or QED Therapeutics' regulatory approval strategies, components of their filings, such as clinical trial designs, conduct and methodologies, or the sufficiency of data submitted for infigratinib for patients with FGFR-driven cancers; the success of and potential synergies from the Agreement and the proposed co-development plan for infigratinib in oncology indications in the United States; the ability of Helsinn Group's unique integrated licensing business model to enable its distribution to reach patients globally; 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; and the timing of these events, 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: the design and success of ongoing and planned clinical trials, future regulatory filings, approvals and/or sales; despite having ongoing and future interactions with the FDA or other regulatory agencies to discuss potential paths to registration of infigratinib, the FDA or such other regulatory agencies may not agree with our regulatory approval strategies, components of our filings, such as clinical trial designs, conduct and methodologies, or the sufficiency of data submitted; the successful closing and continuing success of QED Therapeutics' collaboration with Helsinn Group; potential adverse impacts due to the global COVID-19 pandemic such as delays in regulatory review, manufacturing and supply chain

interruptions, adverse effects on healthcare systems and disruption of the global economy; and those risks set forth in the Risk Factors section of our most recent Annual Report on Form 10-K filed with the U.S. Securities and Exchange Commission (SEC) and our other SEC filings. Moreover, BridgeBio and QED Therapeutics operate in a very competitive and rapidly changing environment in which new risks emerge from time to time. These forward-looking statements are based upon the current expectations and beliefs of BridgeBio's and QED Therapeutics' management as of the date of this release and are subject to certain risks and uncertainties that could cause actual results to differ materially from those described in the forward-looking statements. Except as required by applicable law, we and QED Therapeutics 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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