Helsinn Group and BridgeBio Pharma Announce Update to Strategic Collaboration to Develop, Manufacture and Commercialize Infigratinib in Oncology Indications in the U.S.

- *Helsinn gains an exclusive license to commercialize infigratinib in the U.S.*

Lugano, Switzerland and Palo Alto, CA, March 3, 2022 - Helsinn Group (Helsinn), a fully integrated, global biopharma company with a diversified pipeline of innovative oncology assets and strong track-record of commercial execution, and BridgeBio Pharma, Inc. (Nasdaq: BBIO) (BridgeBio), a commercial-stage biopharmaceutical company that focuses on genetic diseases and cancers, today announced an update to their existing strategic collaboration to develop, manufacture and commercialize infigratinib for oncology indications.

Under the terms of the amended and restated agreement, Helsinn will gain an exclusive license to commercialize infigratinib in the U.S. and will be responsible for developing, manufacturing and commercializing infigratinib in oncology indications worldwide except for achondroplasia or any other skeletal dysplasias and except in mainland China, Hong Kong and Macau. BridgeBio will be eligible to receive regulatory and commercial milestone payments as well as tiered royalties on adjusted net sales from Helsinn. BridgeBio will retain all rights to develop, manufacture and commercialize infigratinib in skeletal dysplasia, including achondroplasia.

In 2021, Helsinn and BridgeBio obtained accelerated approval for TRUSELTIQ™ (infigratinib) from the U.S. Food and Drug Administration (FDA) for the treatment of adults with previously treated, unresectable locally advanced or metastatic cholangiocarcinoma with a fibroblast growth factor receptor 2 (FGFR2) fusion or other rearrangement as detected by an FDA-approved test. Additionally, the two parties received conditional approval by Health Canada and provisional approval by the Therapeutics Goods Association in Australia for TRUSELTIQ™ (infigratinib) for the treatment of adults with previously treated, unresectable locally advanced or metastatic cholangiocarcinoma with a FGFR2 fusion or other rearrangement. Continued approval in the U.S., Canada and Australia for this indication may be contingent upon confirmatory trials.

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

Giorgio Calderari, Helsinn Group CEO commented, "We are delighted to gain the exclusive license to commercialize infigratinib in the U.S. This perfectly complements our recently announced Fully Integrated Targeted Therapy (FITT) Strategy and will utilize our unique capabilities and expertise to take products through development and to patients living with cancer across the globe. BridgeBio is a great partner, and we are looking forward to continuing our relationship with them through our non-exclusive collaboration framework to propose co-development and co-commercialization opportunities for preclinical precision oncology programs."

"We are expanding our partnership with Helsinn so that even more patients with FGFR-driven cancers will ultimately be able to access infigratinib. Focused execution means reducing the scope of our internal activity. We will continue to advance high-quality programs in our pipeline, while allowing Helsinn to develop and commercialize infigratinib in cancer indications for patients in need," **said Neil Kumar, Ph.D., founder and CEO of BridgeBio.**

In March 2021, Helsinn and BridgeBio entered into a global license and collaboration agreement to co-commercialize infigratinib for oncology in the U.S. and to co-develop, manufacture and commercialize infigratinib for such indications outside the U.S., excluding mainland China, Hong Kong and Macau. BridgeBio previously entered a strategic collaboration with LianBio for development and commercialization of infigratinib in oncology indications in mainland China, Hong Kong and Macau.

In November 2021, Helsinn and BridgeBio entered into a strategic collaboration to co-develop and co-commercialize a potentially first-in-class inhibitor designed to target glutathione peroxidase 4 (GPX4), which will be investigated in patients with difficult-to-treat tumors. Alongside this, Helsinn and BridgeBio established a new non-exclusive collaboration framework agreement that allows the companies to propose co-development and co-commercialization opportunities for preclinical precision oncology programs. The terms in this strategic collaboration have not

changed.

About Infigratinib

Infigratinib is a potent orally administered, selective, ATP-competitive, kinase inhibitor of FGFRs, with highest affinity for FGFR 1, 2, and 3. The therapy is currently under investigation as a potential first-line treatment for individuals with FGFR2-altered cholangiocarcinoma (bile duct cancer) and in the adjuvant setting for individuals with FGFR3-altered urothelial carcinoma (bladder cancer). Infigratinib is also in development in skeletal dysplasias for the treatment of individuals with FGFR3-altered achondroplasia. BridgeBio retains full rights to develop and commercialize infigratinib in skeletal dysplasias for the treatment of individuals with FGFR3-altered achondroplasia.

About Cholangiocarcinoma (CCA)

CCA represents an aggressive group of malignancies that form in the bile ducts. Although rare in most countries (with a worldwide estimated incidence of <6 per 100,000 people), the incidence of this malignancy is increasing worldwide. Because the disease is usually asymptomatic at early-stages, diagnosis may be delayed until advanced stages, when CCA typically presents as locally advanced or metastatic disease. Despite continuing advances in treatments, the prognosis for this disease remains poor, with a 5-year survival rate of <20%. FGFR2 genetic alterations are present in approximately 15% to 20% of CCA patients and represent potential targets for treatments.[1,2]

U.S. Indication and Important Safety Information for TRUSELTIQ (infigratinib)

TRUSELTIQ (infigratinib) capsules 25mg/100mg is indicated for the treatment of adults with previously treated, unresectable, locally advanced or metastatic cholangiocarcinoma with a fibroblast growth factor receptor 2 (FGFR2) fusion or other rearrangement as detected by an FDA-approved test.

Accelerated approval was granted based on overall response rate and duration of response. Continued approval for this indication may be contingent upon verification of clinical benefit in confirmatory trial(s).

Warnings and precautions

- **Ocular toxicity:** Retinal pigment epithelial detachment (RPED), which may cause blurred vision, occurred in 11% of 351 patients treated with TRUSELTIQ, including patients with asymptomatic RPED, with a median onset of 26 days. Perform comprehensive ophthalmological exam including optical coherence tomography prior to initiating, at 1 month, at 3 months, and then every 3 months during treatment with TRUSELTIQ. Urgently evaluate patients for onset of visual symptoms and follow up every 3 weeks until resolved or TRUSELTIQ is discontinued. Withhold TRUSELTIQ as recommended. Dry eye occurred in 29% of 351 patients; treat with ocular demulcents as needed
- **Hyperphosphatemia and soft tissue mineralization:** Hyperphosphatemia, which can lead to soft tissue mineralization, cutaneous calcinosis, non-uremic calciphylaxis, vascular calcification, and myocardial calcification, occurred in 82% of 351 patients treated with TRUSELTIQ, with a median time to onset of 8 days (range 1-349); 83% of 351 patients treated with TRUSELTIQ received phosphate binders. Monitor for hyperphosphatemia throughout treatment. Initiate phosphate-lowering therapy for serum phosphate >5.5 mg/dL; withhold TRUSELTIQ and initiate phosphate-lowering therapy for serum phosphate >7.5 mg/dL; withhold, reduce the dose, or permanently discontinue TRUSELTIQ based on duration and severity of hyperphosphatemia
- **Embryo-fetal toxicity:** TRUSELTIQ can cause fetal harm. Advise pregnant women of the potential risk to the fetus; advise females of reproductive potential and men who are partnered with women of reproductive potential to use effective contraception during treatment with TRUSELTIQ and for 1 month after the final dose

Adverse reactions

- **Most common adverse reactions (incidence ≥20%, all grades):** nail toxicity, stomatitis, dry eye, fatigue, alopecia, palmar-plantar erythrodysesthesia syndrome, arthralgia, dysgeusia, constipation, abdominal pain, dry mouth, eyelash changes, diarrhea, dry skin, decreased appetite, blurred vision, and vomiting
- **Most common laboratory abnormalities (incidence ≥20%, all grades):** increased creatinine, increased phosphate, decreased phosphate, increased alkaline phosphatase, decreased hemoglobin, increased alanine aminotransferase, increased lipase, increased

calcium, decreased lymphocytes, decreased sodium, increased triglycerides, increased aspartate aminotransferase (AST), increased urate, decreased platelets, decreased leukocytes, decreased albumin, increased bilirubin, and decreased potassium

Drug interactions

- **CYP3A inhibitors:** Avoid use with strong and moderate CYP3A inhibitors
- **CYP3A inducers:** Avoid use with strong and moderate CYP3A inducers
- **Gastric acid–reducing agents:** Avoid coadministration with proton pump inhibitors, histamine-2 receptor antagonists (H2RA), and locally acting antacids. If coadministration of H2RA or locally acting antacids cannot be avoided, separate TRUSELTIQ administration
    - **H2RA:** Take TRUSELTIQ 2 hours before or 10 hours after
    - **Locally-acting antacid:** Take TRUSELTIQ 2 hours before or 2 hours after

Dosage and administration

- **Prior to initiating TRUSELTIQ:** Confirm FGFR2 fusion or rearrangement; perform comprehensive ophthalmic exam including OCT; confirm negative pregnancy test in females of reproductive potential
- **Starting dose:** Take TRUSELTIQ orally once daily on Days 1-21 of 28-day cycles; continue treatment until disease progression or unacceptable toxicity. Take TRUSELTIQ on an empty stomach with a glass of water at least 1 hour before or 2 hours after food
    - No renal or hepatic impairment
        - 125 mg (one 100 mg capsule and one 25 mg capsule)
    - Mild and moderate renal impairment (creatinine clearance 30-89 mL/min)
        - 100 mg (one 100 mg capsule)
    - Mild hepatic impairment (total bilirubin >upper limit of normal [ULN] to 1.5 x ULN or AST > ULN)
        - 100 mg (one 100 mg capsule)
    - Moderate hepatic impairment (total bilirubin >1.5 to 3 x ULN with any AST)
        - 75 mg (three 25 mg capsules)
- **Dose modification:** Consult the TRUSELTIQ full Prescribing Information for dose modifications and monitoring recommendations for RPED, hyperphosphatemia, and other

Grades 3-4 adverse reactions

For additional information, please see the U.S. Full Prescribing Information for TRUSELTIQ

References

[1]Banales, J., Cardinale, V., Carpino, G. et al. Cholangiocarcinoma: current knowledge and future perspectives consensus statement from the European Network for the Study of Cholangiocarcinoma (ENS-CCA). Nat Rev Gastroenterol Hepatol 13, 261–280 (2016). https://doi.org/10.1038/nrgastro.2016.51

[2] Banales, J.M., Marin, J.J.G., Lamarca, A. et al. Cholangiocarcinoma 2020: the next horizon in mechanisms and management. Nat Rev Gastroenterol Hepatol 17, 557–588 (2020). https://doi.org/10.1038/s41575-020-0310-z

About Helsinn Group

Helsinn is a fully integrated, global biopharma company headquartered in Lugano, Switzerland. It is focused on improving the lives of cancer patients all over the world with a leading position in cancer supportive care and an innovative pipeline of cancer therapeutics.

Helsinn is a third-generation family-owned company, that since 1976 has been focused on improving the lives of patients, guided by core values of respect, integrity and quality. It operates a unique licensing business model with integrated drug development and manufacturing capabilities. Helsinn has a commercial presence in 190 countries either directly, with operating subsidiaries in the U.S. and China, or via its network of long-standing trusted partners. Helsinn also has a fully integrated supply chain and product development through its subsidiary in Ireland, Helsinn Birex Pharmaceuticals Ltd.

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 and LinkedIn.

About BridgeBio Pharma, Inc.

BridgeBio Pharma, Inc. (BridgeBio) is a commercial-stage 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 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. BridgeBio Pharma, Inc. ("BridgeBio," "we," "us" or "our") intends 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. These forward-looking statements, including statements relating to the clinical and therapeutic potential of our programs and product candidates, expectations, plans and prospects regarding clinical development plans; regulatory status and commercial strategy; the success of BridgeBio and Helsinn's continued partnership, including the ability of both companies to co-develop, manufacture and commercialize infigratinib for certain indications; BridgeBio's eligibility to receive future royalty and other payments under the updated strategic collaboration with Helsinn and the timing of these events; the success of the non-exclusive framework between BridgeBio and Helsinn to allow the companies to propose additional co-development and co-commercialization collaborations for other preclinical precision oncology programs; the ability of the collaboration to magnify the ability of both companies to identify small oncology interventions that may have

greater potential to help patients in combination with larger investigational therapies; the belief that the combination of BridgeBio's early preclinical development and Helsinn's global commercial platform will help to accelerate the identification and development of therapeutic options for patients; the ability of BridgeBio and Helsinn to jointly develop and commercialize a potentially first-in-class inhibitor designed to target GPX4 to provide an effective new therapy for patients with difficult-to-treat tumors; the timing and cadence of updating the market on infigratinib, GPX4 and additional programs; and BridgeBio's faith in the long-term prospects of its pipeline, reflect our current views about our plans, intentions, expectations and strategies, which are based on the information currently available to us and on assumptions we have made. Although we believe that our plans, intentions, expectations and strategies 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, initial and ongoing data from our preclinical studies and clinical trials not being indicative of final data, the potential size of the target patient populations our product candidates are designed to treat not being as large as anticipated, 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 for our product candidates, the FDA or such other regulatory agencies not agreeing with our regulatory approval strategies, components of our filings, such as clinical trial designs, conduct and methodologies, or the sufficiency of data submitted, the continuing success of BridgeBio's collaborations, including various collaborations between BridgeBio and Helsinn, 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, as well as those risks set forth in the Risk Factors section of BridgeBio's Annual Report on Form 10-K for the year ended December 31, 2021 and our other filings with the U.S. Securities and Exchange Commission. Moreover, BridgeBio and Helsinn 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 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 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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