NEWS RELEASE

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

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Pivotal study demonstrated a clinically meaningful rate of tumor shrinkage (overall response rate) and duration of response in patients with previously-treated advanced cholangiocarcinoma (CCA) harboring an FGFR2 fusion or rearrangement

BridgeBio, through its affiliate QED ("BridgeBio"), and Helsinn will co-commercialize TRUSELTIQ in the U.S.

TRUSELTIQ is BridgeBio's first FDA approved therapeutic in oncology and second approved therapeutic this year

PALO ALTO, Calif. and LUGANO, Switzerland, May 28, 2021 (GLOBE NEWSWIRE) -- BridgeBio Pharma, Inc. (Nasdaq: BBIO), through its affiliate QED Therapeutics, Inc., and Helsinn Group today announced that the US Food and Drug Administration (FDA) has approved TRUSELTIQ™ (infigratinib) under the accelerated approval program for the treatment of patients with previously-treated locally advanced or metastatic cholangiocarcinoma (CCA) harboring an FGFR2 fusion or rearrangement. TRUSELTIQ is an orally administered, ATP-competitive, tyrosine kinase inhibitor of FGFR. In the pivotal trial of patients with advanced, unresectable CCA, an aggressive malignancy with poor prognosis, TRUSELTIQ led to cases of tumor shrinkage. CCA is known to affect approximately 20,000 people in the United States and European Union each year and has a median five-year survival rate of only 9%.[1]

"This is an important milestone for patients diagnosed with FGFR2-fusion-driven cholangiocarcinoma who have

recurred after first-line therapy and are in need of targeted options for further treatment," said Susan Moran, M.D., M.S.C.E., Chief Medical Officer for QED. "Based on the efficacy seen to date, our team believes infigratinib possesses promise for a range of FGFR-driven conditions, including other cancers. We will continue to evaluate its safety and efficacy in these areas of unmet need."

The approval of TRUSELTIQ is based on a Phase 2 clinical study in which 108 patients who had undergone at least one prior treatment for advanced CCA received 125 mg of TRUSELTIQ daily for 21 days of 28-day cycles. Of these patients, 107 (99%) had Stage IV CCA. All patients had received at least 1 prior line of systemic therapy. The study's primary endpoint demonstrated a confirmed objective response rate (ORR) of 23% (95% CI 16-32%). The study also showed a median duration of response (DOR) of 5.0 months (95% CI 3.7–9.3 months). Common adverse reactions and laboratory abnormalities (of >30%) were increased creatinine, increased phosphate, decreased phosphate, nail toxicity, stomatitis, increased alkaline phosphatase, decreased hemoglobin, increased alanine aminotransferase, dry eye, fatigue, increased lipase, decreased lymphocytes, increased calcium, decreased sodium, alopecia, increased triglycerides, increased aspartate aminotransferase, decreased platelets, increased urate, palmar-plantar erythrodysesthesia syndrome, arthralgia, and dysgeusia. Please see below for additional important safety information for TRUSELTIQ.

The above data were presented at the 2021 American Society of Clinical Oncology Gastrointestinal Cancers Symposium by the lead investigator, Milind Javle, M.D., Professor of Gastrointestinal Medical Oncology at The University of Texas MD Anderson Cancer Center.

"While targeted treatments have extended survival for many types of cancer, people diagnosed with cholangiocarcinoma have previously been presented with extremely limited treatment options coupled with low statistical survival data," said Dr. Javle. "In this study, TRUSELTIQ showed promise as a targeted treatment option for patients with FGFR2-fusion-driven cholangiocarcinoma with a well-tolerated safety profile in line with previous observations in this patient population."

"The approval of TRUSELTIQ provides a new and exciting treatment option for patients with CCA harboring an FGFR2 fusion," said Stacie Lindsey, Chief Executive Officer of the Cholangiocarcinoma Foundation. "We appreciate the fact that there is a robust patient support program, ForgingBridges, to help patients access care and support them throughout their treatment journey."

Additional marketing applications for infigratinib are 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.

BridgeBio and Helsinn Group's affiliate, Helsinn Therapeutics (U.S.), Inc., will be jointly responsible for

commercialization activities 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 and Helsinn Group entered into a global collaboration and licensing agreement in March 2021. BridgeBio previously entered a strategic collaboration with LianBio for development and commercialization of infigratinib in oncology indications in China, Hong Kong and Macau.

Paul Rittman, Chief Executive Officer of Helsinn Therapeutics, said, "Today's FDA approval of TRUSELTIQ for patients with previously-treated locally advanced or metastatic CCA harboring an FGFR2 fusion or rearrangement provides a new therapy option for patients with a very low rate of survival. This new therapy has the potential to make a life changing impact on patients with few treatment options, and Helsinn Therapeutics looks forward to working with BridgeBio to make it widely accessible to health care providers and patients in the US."

ForgingBridges | TRUSELTIQ is a comprehensive patient support program designed specifically to provide education, access and affordability resources for patients during their TRUSELTIQ journey. For more information, visit: TRUSELTIQ.com/forgingbridges-overview.

Visit **TRUSELTIQ.com** for more information, including full **Prescribing Information**.

About TRUSELTIQ™ (infigratinib)
TRUSELTIQ (infigratinib) is an orally administered, ATP-competitive, tyrosine kinase inhibitor of FGFR, approved for the treatment of individuals with FGFR2 fusion-driven cholangiocarcinoma (bile duct cancer). TRUSELTIQ targets the fibroblast growth factor receptor (FGFR) protein, blocking downstream activity. In clinical studies, TRUSELTIQ demonstrated a clinically meaningful rate of tumor shrinkage (overall response rate) and duration of response. Visit **TRUSELTIQ.com** for more information. Infigratinib is not FDA approved for any other indication in the U.S. and is not approved for use by any other health authority. It is currently being evaluated in clinical studies for first-line cholangiocarcinoma and urothelial carcinoma (bladder cancer). For more information, visit **QEDTx.com**.

About Cholangiocarcinoma (CCA)
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, the five-year survival rate is only 9%.[1] Advanced, unresectable CCA is a rare, aggressive malignancy with a poor prognosis.

Clinical Studies[1]

The efficacy of TRUSELTIQ was based on a single-arm Phase 2 study which included 108 patients with previously treated, unresectable locally advanced or metastatic cholangiocarcinoma with an FGFR2 fusion or rearrangement. Ninety-nine percent of patients had metastatic (Stage IV) disease at the time of study entry.

These 108 adult patients with advanced/metastatic CCA received infigratinib 125 mg orally for 21 days of each 28-day cycle until unacceptable toxicity or disease progression. All patients received prophylaxis with the oral phosphate binder sevelamer. TRUSELTIQ achieved a 23% objective response rate (ORR) and a median duration of response (DOR) of 5.0 months.

U.S. Indication for TRUSELTIQ
TRUSELTIQ 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).

U.S. Important Safety Information for TRUSELTIQ
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

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, FGFR 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
For more information, please visit **QEDTx.com**.

About BridgeBio Pharma, Inc.
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 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 the Group's products directly in these countries. The Group 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). 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 **helsinn.com** and follow us on **Twitter**, **LinkedIn** and **Vimeo**.

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 the United States; Helsinn’s exclusive commercialization rights outside of the United States, excluding China, Hong Kong and Macau; the success and expected timing of the closing of the BridgeBio and Helsinn global collaboration and licensing agreement; the potential for TRUSELTIQ to treat a range of FGFR-driven conditions, including other cancers; the promise of TRUSELTIQ as a targeted treatment option for patients with FGFR2 fusion driven CCA with a well-tolerated safety profile in line with previous observations in this patient population; the success of QED’s comprehensive patient support program, ForgingBridges, designed specifically to provide education, access and affordability resources for patients during their TRUSELTIQ journey; the success of TRUSELTIQ as a new therapy option for patients with previously-treated locally advanced or metastatic CCA harboring an FGFR2 fusion or rearrangement that typically have a very low rate of survival; the efficacy of TRUSELTIQ for the treatment of adults with previously treated, unresectable locally advanced or metastatic cholangiocarcinoma with a FGFR2 fusion or other rearrangement as detected by a U.S. Food and Drug Administration (FDA)-approved test; 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 FDA-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 or other regulatory agencies, the FDA 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 the FDA 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 success and expected closing (and the timing thereof) of the BridgeBio and Helsinn global collaboration and licensing agreement; 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, 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

[1] Dhanasekaran, R., Hemming, A. W., Zendejas, I., George, T., Nelson, D. R., Soldevila-Pico, C., Firpi, R. J., Morelli, G., Clark, V., Cabrera, R. "Treatment outcomes and prognostic factors of intrahepatic cholangiocarcinoma". Oncology Reports 29.4 (2013): 1259-1267.

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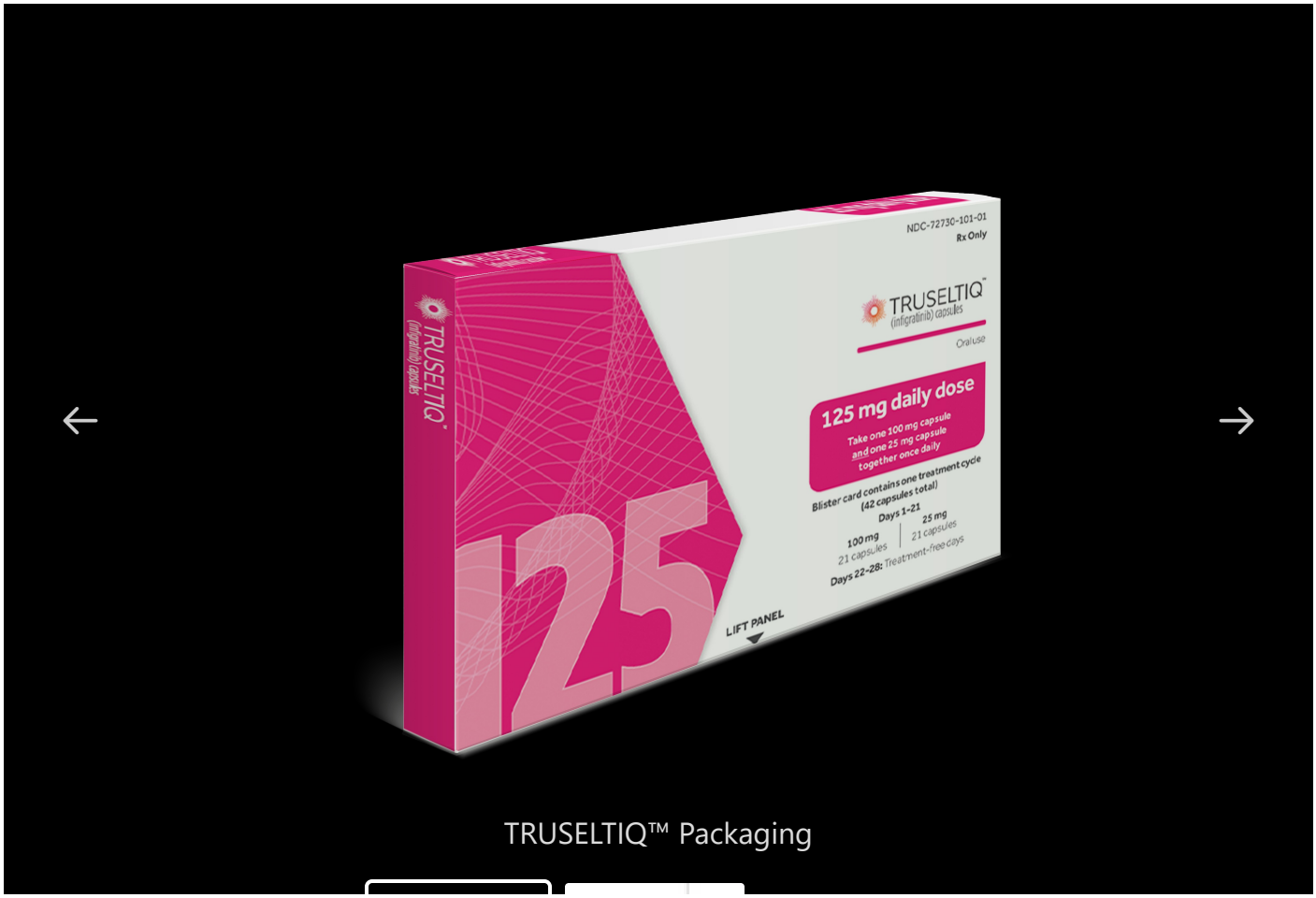
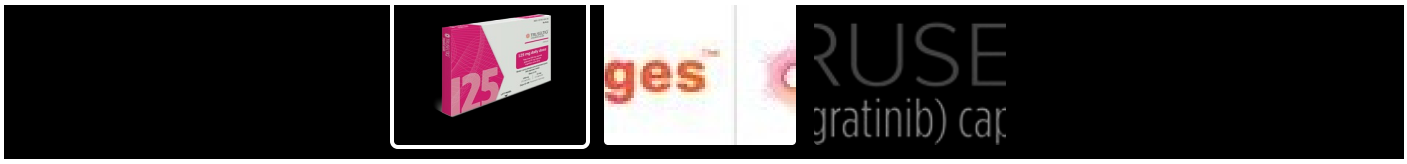


TRUSELTIQ™ Packaging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