Helsinn and Xediton sign exclusive license and distribution agreement for TRUSELTIQ™ (infigratinib) in Canada

Lugano, Switzerland, and Mississauga, Ontario, 20 December 2021 – Helsinn Group (Helsinn), 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, and Xediton Pharmaceuticals Inc. (Xediton), a Canadian based specialty pharmaceutical company with a strong presence in products in Oncology, announced today the signing of an exclusive license and distribution agreement in Canada for TRUSELTIQ™ (infigratinib), which was recently approved under Health Canada's 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 fibroblast growth factor receptor 2 (FGFR2) fusion or other rearrangement.

Under the terms of the license and distribution agreement, Helsinn Healthcare SA grants Xediton an exclusive license to distribute, promote, market, and sell TRUSELTIQ in Canada and Helsinn will supply TRUSELTIQ for commercialization in Canada. TRUSELTIQ has been reviewed in Canada under Project Orbis, an initiative of the U.S. Food and Drug Administration's (FDA's) Oncology Center of Excellence that allows for concurrent submission and review of oncology drugs among participating international regulatory agencies.

Riccardo Braglia, Helsinn Group Vice Chairman and CEO commented, "We are very pleased to have signed this agreement with Xediton for the distribution of TRUSELTIQ in Canada. This marks an important step in our TRUSELTIQ commercialization strategy. We look forward to continuing to work closely with Xediton to ensure that this treatment reaches the Canadian patients that could most benefit from it."

George Gafrey, President of XEDITON Pharmaceuticals Inc., commented: "We are very pleased to partner with Helsinn Group to bring TRUSELTIQ to Canadian patients. We believe the imminent launch of TRUSELTIQ will fill a gap in the much-needed therapy for cancer patients. We look forward to TRUSELTIQ being on the market."

About TRUSELTIQ™ (infigratinib)

TRUSELTIQ (infigratinib) is a small molecule kinase inhibitor that targets FGFR, which was conditionally approved by Health Canada 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.

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.

About Cholangiocarcinoma (CCA)

CCA (bile duct cancer) 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. 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]

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.

TRUSELTIQ is a trademark of Helsinn Group.

About the 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 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 over 190 countries either directly, with operating subsidiaries in the U.S. and China, or via its network of long-standing trusted partners.

Helsinn 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.

To learn more about Helsinn Group please visit www.helsinn.com

About Xediton Pharmaceuticals

Xediton Pharmaceuticals is a privately-held pharmaceutical company with a focus on meeting the needs of patients, physicians and partners. Xediton Pharmaceuticals is committed to developing, partnering and making available new and established medicines to promote the health of Canadians. Located in the Greater Toronto Area, Canada, Xediton Pharmaceuticals has products in Oncology, Anti-Infectives, Pain, GI, Ophthalmology and CV and has built strong strategic alliances with Global and International Healthcare and pharmaceutical companies.

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

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