

## **Helsinn Group Announces European Medicines Agency's (EMA) Acceptance for review of the Marketing Authorization Application (MAA) for Infigratinib for Patients with Cholangiocarcinoma with Fibroblast Growth Factor Receptor 2 Fusions or Rearrangements**

**Lugano, Switzerland, December 21, 2021** - Helsinn Group ("Helsinn"), a fully integrated, global biopharma company with a diversified pipeline of innovative oncology assets and strong track-record of commercial execution, today announced that the European Medicines Agency (EMA) accepted for review the Company's Marketing Authorization Application (MAA) for infigratinib 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. The EMA's acceptance for review of the MAA confirms that the submission is complete and the formal review process can begin.

In March 2021, Helsinn Group entered a strategic collaboration with QED Therapeutics, an affiliate company of BridgeBio Pharma, Inc., a commercial-stage biopharmaceutical company focused on genetic diseases and cancers, to co-develop and co-commercialize infigratinib in oncology indications worldwide except in China, Hong Kong and Macau.

**Sergio Cantoreggi, Helsinn Group Chief Scientific Officer and Global Head of R&D, commented:** "The acceptance for review of our MAA is a significant step towards bringing infigratinib to patients in the European Union. There is a great need for new therapies in bile duct cancer for patients who have relapsed after first-line therapy and need further targeted treatment. This acceptance opens the review process for infigratinib and we look forward to working closely with the EMA to potentially bring this novel therapy to patients in need."

### **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 in development in oncology for the treatment of individuals with FGFR2-altered cholangiocarcinoma (bile duct cancer) and FGFR3-altered urothelial carcinoma (bladder cancer) and in skeletal dysplasias for the treatment

of individuals with FGFR3-altered achondroplasia. BridgeBio retains full rights to infigratinib in skeletal dysplasias for the treatment of individuals with FGFR3-altered achondroplasia.

For details on approvals by Health Authorities, please visit <https://helsinn.com/> to access product details. Product labeling from various countries or regions may differ based on the study design requirements of the Health Authority for the respective jurisdiction.

### **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%.<sup>1</sup>

### **References**

<sup>1</sup> 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.

### **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 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](http://www.helsinn.com)

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