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Juniper Biologics inks oncology deal with Helsinn for emerging markets

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The agreement is to develop and commercialise infigratinib (INN) in Australia, New Zealand, Southeast Asia and certain markets in the Middle East and Africa

Singapore-based Juniper Biologics, a science-led healthcare company focused on researching, developing and commercializing novel therapies, and Helsinn Group, a fully integrated, global biopharma company with a diversified pipeline of innovative oncology assets and strong track-record of commercial execution, has announced the signing of an exclusive license agreement to develop and commercialise infigratinib (INN) in Australia, New Zealand, Southeast Asia and certain markets in the Middle East and Africa 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.

In 2021 infigratinib obtained accelerated approval from the U.S. Food and Drug Administration (FDA) under the brand name "TRUSELTIQ" 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.

This indication is based on overall response rate and duration of response. Additionally, infigratinib received conditional approval by Health Canada and provisional approval by the Therapeutics Goods Association in Australia 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 verification and description of clinical benefit in confirmatory trial(s).

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.