

Helsinn Group announces oral presentation of data at AACR-NCI-EORTC relating to a potent and highly selective investigational RET inhibitor

Lugano, Switzerland, 7 October 2021 – Helsinn Group, 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, today announces the acceptance of two abstracts on a potent and highly selective RET inhibitor at the AACR-NCI-EORTC Virtual International Conference on Molecular Targets and Cancer Therapeutics, taking place from 7-10 October.

One abstract has been accepted for oral presentation and shows findings on TAS0953/HM06, the selective RET inhibitor under investigation in non-small cell lung cancer (NSCLC) and other cancers. The abstract is entitled *Discovery of TAS0953/HM06, a novel next generation RET-specific inhibitor capable of inhibiting RET solvent front mutations*. Extensive preclinical data is being developed to assess TAS0953/HM06. Preliminary results demonstrate potency against the RET solvent front mutation resistance mechanism. Full details of the presentation are below:

- **Date:** Saturday 9 October
- **Plenary Session 6:** New Drugs on the Horizon II
- **Time:** 16:25-16:40 ET
- **Presenter:** Isao Miyazaki

In addition to the oral presentation, the second abstract has been accepted as a video poster entitled *TAS0953/HM06 is effective in preclinical models of diverse tumor types driven by RET alterations*. This second abstract highlights the investigational compound's activity across tumor types such as lung, thyroid carcinomas and soft-tissue sarcoma.

A Phase 1/2 clinical trial is ongoing for TAS0953/HM06, an investigational oral treatment which is evaluating inhibition of several RET abnormalities identified as oncogenic driver alterations in NSCLC, papillary and medullary thyroid cancers, and several other tumor types. This innovative

drug candidate offers several differentiating features.

Sergio Cantoreggi, Group Chief Scientific Officer and Group Head of R&D commented: “We are pleased to be sharing this important pre-clinical data on TAS0953/HM06 at AACR-NCI-EORTC. Although first-generation selective RET inhibitors show clinical antitumor activity in NSCLC, acquired resistances driven by RET solvent front mutations have emerged. TAS0953/HM06 is currently under investigation in a Phase 1/2 clinical trial and we will continue to work closely with Taiho as further data emerge. We remain hopeful that this investigational compound could offer significant benefits for patients with NSCLC and other tumors that harbor RET abnormalities.”

TAS0953/HM06 is an investigational agent and is not approved for commercial use in any country.

About TAS0953/HM06

TAS0953/HM06 is an oral potent and highly selective RET inhibitor in development for advanced or metastatic Non-Small Cell Lung Cancer (NSCLC) and other tumors which express RET gene abnormalities.

Taiho Pharmaceutical Co., Ltd. and Helsinn signed a co-development and commercialization agreement for TAS0953/HM06 in 2017 and will continue to pursue together all preclinical, clinical and CMC developments. This alliance also includes efforts to reach as many patients as possible around the world through their own commercial infrastructures or through valued partners.

About RET abnormalities in NSCLC and other cancers¹

RET kinase abnormalities have been identified as targetable oncogenic drivers in NSCLC, papillary and medullary thyroid cancers, and several other tumor types. In NSCLC, RET fusions are more common in younger patients with no prior history of smoking and in those with adenocarcinomas, however the underlying mechanisms remain unknown.

References

1 Helsinn and Taiho research and analysis of ASCO 2018; ASCO 2019; Cancer Biol Ther 2015; Cell Rep 2017; JCO 2018; Johns Hopkins 2019; Nat Med 2012; Nat Rev Clin Oncol 2018; OMIM; Onco Targets Ther 2019

About the Helsinn Group

Helsinn is 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, thanks to a consolidated track record, a solid revenue stream in B2B and strong cash flow and cash position.

Helsinn is building market differentiation in B2C in the U.S. and China and is owned by a third-generation healthcare entrepreneurial family.

Since 1976, Helsinn has been improving the lives of patients, guided by core family values of respect, integrity and quality and through a unique integrated licensing business model, and by collaborating with success in about 190 countries with long-standing partners, 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).

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.

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

About Taiho Pharmaceutical Co., Ltd. (Japan)

Taiho Pharmaceutical, a subsidiary of Otsuka Holdings Co., Ltd., is an R&D-driven specialty pharma company with a focus on oncology. Taiho Pharmaceutical also has development programs in allergy and immunology, urology and consumer healthcare products. Our corporate philosophy is simple: “We strive to improve human health and contribute to a society enriched by smiles.”

For more information about Taiho Pharmaceutical, please visit: <https://www.taiho.co.jp/en/>

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