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Building quality cancer care together

## Helsinn announces FDA acceptance of IND application for TAS0953/HM06 in Patients with Advanced Solid Tumors with RET Gene Abnormalities

**Lugano, Switzerland, June 8, 2020**: Helsinn, a Swiss pharmaceutical group focused on building quality cancer care and rare diseases products, today announced that on April 1, 2020 the U.S. Food and Drug Administration (FDA) completed the review of the Investigational New Drug (IND) application for TAS0953/HM06 and released a "Study May Proceed" letter for the Phase 1/2 Study of TAS0953/HM06 in Patients with Advanced Solid Tumors with RET Gene Abnormalities.

The study is intended to be conducted globally and is due to commence in the third quarter of 2020.

TAS0953/HM06 is being developed together with its partner Taiho Pharmaceutical Co., Ltd. In 2017, Helsinn and Taiho signed a global co-development and commercialization agreement for TAS0953/HM06.

TAS0953/HM06 is an investigational oral treatment which inhibits 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 as compared to other RET inhibitors.

**Sergio Cantoreggi, Group Chief Scientific Officer and Head of R&D at Helsinn, commented**: "Helsinn and Taiho have been working closely together as part of a global development partnership and we're delighted to have reached this latest milestone that will allow us to start treating patients with TAS0953/HM06 in a Phase 1/2 clinical trial starting in the next quarter. We are excited by the potential of TAS0953/HM06 to treat NSCLC and other tumors which harbor RET abnormalities and look forward to working with Taiho to progress the treatment through the clinic."

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

### About TAS0953/HM06

TAS0953/HM06 is an oral RET inhibitor in development for advanced or metastatic Non-Small Cell Lung Cancer (NSCLC) and other tumors which express RET gene abnormalities. Preclinical data showed several differentiating features in comparison to other targeted therapies acting on RET

abnormalities.

Taiho 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 cancers[1]**

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.

[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

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**About the 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 acquisition to address unmet medical needs. Helsinn operates a unique integrated licensing business model, achieving success with over 80 long-standing partners in 190 countries, who share our values. The Group's pharmaceutical business (Helsinn Healthcare) is headquartered in Lugano, Switzerland with operating subsidiaries in the U.S. (Helsinn Therapeutics US) and China (Helsinn Pharmaceuticals China) which market the Group's products directly in these countries. The Group has additional operating subsidiaries in Switzerland (Helsinn Advanced Synthesis, an active pharmaceutical ingredient manufacturer) and Ireland (Helsinn Birex Pharmaceuticals, a drug product manufacturer). 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.

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

**About Taiho Pharmaceutical**

Taiho Pharmaceutical, a subsidiary of Otsuka Holdings Co., Ltd., is an R&D-driven specialty pharma focusing on the three fields of oncology, allergy and immunology, and urology. Its corporate philosophy takes the form of a pledge: “We strive to improve human health and contribute to a society enriched by smiles.” In the field of oncology in particular, Taiho Pharmaceutical is known as a leading company in Japan for developing innovative medicines for the treatment of cancer, a reputation that is rapidly expanding through their extensive global R&D efforts. In areas other than oncology, as well, the company creates and markets quality products that effectively treat medical conditions and can help improve people's quality of life. Always putting customers first, Taiho Pharmaceutical also aims to offer consumer healthcare products that support people's efforts to lead fulfilling and rewarding lives. For more information about Taiho Pharmaceutical, please visit: https://www.taiho.co.jp/en/

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