HUTCHMED announces savolitinib approved in China for patients with lung cancer with MET exon 14 skipping alterations

– First selective MET inhibitor approval in China in this setting –

– First regulatory approval for the oral, potent and selective MET tyrosine kinase inhibitor –

Hong Kong, Shanghai & Florham Park, NJ —Tuesday, June 22, 2021: HUTCHMED (China) Limited ("HUTCHMED") (Nasdaq/AIM: HCM) today announces that AstraZeneca PLC ("AstraZeneca") and HUTCHMED's savolitinib has been granted conditional approval in China for the treatment of patients with non-small cell lung cancer ("NSCLC") with MET exon 14 skipping alterations who have progressed following prior systemic therapy or are unable to receive chemotherapy. This approval follows a priority review designation by China's National Medical Products Administration ("NMPA") and marks the first regulatory approval globally for this oral, potent and selective MET tyrosine kinase inhibitor ("TKI").

Approximately 2-3% of newly diagnosed NSCLC patients have MET exon 14 skipping alterations, a specific genetic mutation.

The approval by the NMPA was based on positive results from a Phase II trial conducted in China in patients with NSCLC with this mutation, including patients with the more aggressive pulmonary sarcomatoid carcinoma subtype. Savolitinib demonstrated effective anti-tumor activity based on an independent review of objective response rate ("ORR") and disease control rate ("DCR"). The approval is conditional upon successful completion of a confirmatory study in this patient population.

Christian Hogg, Chief Executive Officer of HUTCHMED, said: "It is with great pleasure that today we announce the first regulatory approval of savolitinib globally, HUTCHMED's third self-discovered oncology drug to be commercialized. Our collaboration with AstraZeneca in 2011 has been an important driver in the development of this novel targeted oncology drug, involving both a China-based biotech and a global pharma company. This approval is a testament to the perseverance and scientific ingenuity of this long-standing alliance, and we are hopeful that this is only the beginning of the progress we can achieve for patients with MET-altered tumors."

Dave Fredrickson, Executive Vice President, Oncology Business Unit of AstraZeneca, said: "This approval makes savolitinib the only targeted medicine approved for these biomarker-selected patients in China, and it adds another novel medicine to our already diverse lung cancer portfolio. We are proud that this first-ever regulatory approval of savolitinib is in China, where we have a long-standing commitment to improving patient outcomes and working with the right partners to achieve that goal. Alongside HUTCHMED, we look forward to the continued development of this medicine across a range of cancers where MET alterations and amplification are drivers of tumor growth and treatment resistance."

About savolitinib

Savolitinib is an oral, potent and selective MET TKI that has demonstrated clinical activity in advanced solid tumors. It blocks atypical activation of the MET receptor tyrosine kinase pathway that occurs because of mutations (such as exon 14 skipping alterations).

Savolitinib is currently under development for multiple tumor types, including lung, kidney and gastric cancers, as a single treatment and in combination with other medicines.

HUTCHMED and AstraZeneca collaboration

In 2011, HUTCHMED and AstraZeneca entered a global licensing agreement with respect to the development and commercialization of savolitinib. HUTCHMED is responsible for the manufacturing and supply of savolitinib, and AstraZeneca is responsible for its commercialization in China and worldwide.

About HUTCHMED

HUTCHMED (Nasdaq/AIM: HCM) (formerly Hutchison China MediTech) is an innovative, commercial-stage, biopharmaceutical company. It is committed to the discovery and global development and commercialization of targeted therapies and immunotherapies for the treatment of cancer and immunological diseases. A dedicated organization of over 1,300 personnel has advanced ten cancer drug candidates from in-house discovery into clinical studies around the world, with its first two oncology drugs now approved and launched. For more information, please visit: www.hutch-med.com or follow us on LinkedIn.

About AstraZeneca in lung cancer

AstraZeneca is working to bring patients with lung cancer closer to cure through the detection and treatment of early-stage disease, while also pushing the boundaries of science to improve outcomes in the resistant and advanced settings. By defining new therapeutic targets and investigating innovative approaches, the Company aims to match medicines to the patients who can benefit most.

AstraZeneca's comprehensive portfolio includes leading lung cancer medicines and the next wave of innovations including TAGRISSO® (osimertinib) and IRESSA® (gefitinib); IMFINZI® (durvalumab) and tremelimumab; ENHERTU® (trastuzumab deruxtecan) and datopotamab deruxtecan in collaboration with Daiichi Sankyo; savolitinib in collaboration with HUTCHMED; as well as a pipeline of potential new medicines and combinations across diverse mechanisms of action.

AstraZeneca is a founding member of the Lung Ambition Alliance, a global coalition working to accelerate innovation and deliver meaningful improvements for people with lung cancer including and beyond treatment.

About AstraZeneca in oncology

AstraZeneca is leading a revolution in oncology with the ambition to provide cures for cancer in every form, following the science to understand cancer and all its complexities to discover, develop and deliver life-changing medicines to patients.

AstraZeneca's focus is on some of the most challenging cancers. It is through persistent innovation that AstraZeneca has built one of the most diverse portfolios and pipelines in the industry, with the potential to catalyze changes in the practice of medicine and transform the patient experience.

AstraZeneca has the vision to redefine cancer care and, one day, eliminate cancer as a cause of death.

About AstraZeneca

AstraZeneca (LSE/STO/Nasdaq: AZN) is a global, science-led biopharmaceutical company that focuses on the discovery, development and commercialization of prescription medicines in Oncology and BioPharmaceuticals, including Cardiovascular, Renal & Metabolism, and Respiratory & Immunology. Based in Cambridge, UK, AstraZeneca operates in over 100 countries and its innovative medicines are used by millions of patients worldwide. Please visit astrazeneca.com and follow the company on Twitter @AstraZeneca.

Forward-Looking Statements

This announcement contains forward-looking statements within the meaning of the "safe harbor" provisions of the U.S. Private Securities Litigation Reform Act of 1995. These forward-looking statements reflect HUTCHMED's current expectations regarding future events, including its expectations regarding the commercial launch of savolitinib in China, our ability to manufacture and supply savolitinib, the ability of its partner AstraZeneca to distribute savolitinib quickly and broadly, the potential market for savolitinib in non-small cell lung cancer patients China, and the further clinical development for savolitinib in these and other indications and in combination with other medicines in China, the United States and other jurisdictions. Forward-looking statements involve risks and uncertainties. Such risks and uncertainties include, among other things, assumptions regarding AstraZeneca's ability to effectively commercialize savolitinib, the benefits obtained from savolitinib during clinical trials being the same for all patients who are prescribed savolitinib, no unidentified side effects occurring which could result in the NMPA pulling savolitinib from the market, AstraZeneca and HUTCHMED's ability to fund, implement and complete further clinical development and commercialization plans for savolitinib, the timing of these events, and the impact of the COVID-19 pandemic on general economic, regulatory and political conditions. In addition, as certain studies rely on the use of TAGRISSO® and IMFINZI® as combination therapeutics with savolitinib, such risks and uncertainties include assumptions regarding the safety, efficacy, supply and continued regulatory approval of these therapeutics. Existing and prospective investors are cautioned not to place undue reliance on these forward-looking statements, which speak only as of the date hereof. For further discussion of these and other risks, see HUTCHMED's filings with the U.S. Securities and Exchange Commission and on AIM. HUTCHMED undertakes no obligation to update or revise the information contained in this announcement, whether as a result of new information, future events or circumstances or otherwise.

Inside Information

This announcement contains inside information for the purposes of Article 7 of Regulation (EU) No 596/2014.

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