HUTCHMED Announces Agreement with NHSA for Inclusion of ORPATHYS® in the National Reimbursement Drug List in China

Hong Kong, Shanghai & Florham Park, NJ — Wednesday, January 18, 2022: HUTCHMED (China) Limited ("HUTCHMED") (Nasdaq/AIM: HCM; HKEX:13) today announces, following negotiations with the China National Healthcare Security Administration ("NHSA"), ORPATHYS® (savolitinib) has been included in the updated National Reimbursement Drug List ("NRDL") for the treatment of locally advanced or metastatic non-small cell lung cancer ("NSCLC") adult patients with MET exon 14-skipping alterations who have progressed after or unable to tolerate platinum-based chemotherapy. The updated NRDL will take effect from March 1, 2023.

Savolitinib, marketed in China under the brand name ORPATHYS®, is an oral, potent and highly selective MET tyrosine kinase inhibitor ("TKI") jointly developed by AstraZeneca and HUTCHMED with HUTCHMED taking the lead in China, and commercialized by AstraZeneca worldwide.

Dr Weiguo Su, Chief Executive Officer and Chief Scientific Officer of HUTCHMED, said: "The NRDL has significantly broadened access to novel medicines for Chinese patients. We are gratified to see that our third novel oncology medicine, ORPATHYS®, will be included in this year's NRDL update. As the first and only selective MET inhibitor in the market, the inclusion of ORPATHYS® will increase the affordability and access to this novel treatment."

Leon Wang, Executive Vice President, International and China President of AstraZeneca, said: "The inclusion of ORPATHYS® on the NRDL is exciting news for NSCLC patients in China with MET exon 14 skipping alterations who will now have improved access to the only targeted medicine approved in this setting and who often do not respond well to chemotherapy. Since its launch in mid-2021, ORPATHYS® has helped patients in need achieve better outcomes, and we are excited about the potential to reach even more patients in China with this transformational medicine."

ORPATHYS® received conditional approval in China in June 2021 for the treatment of certain patients with NSCLC with MET exon 14 skipping alterations.

About the NRDL

In recent years, the government in China has placed great importance on improving the affordability of drug treatments for the public. The NHSA regularly convenes a broad network of experts in medicine, pharmacology and pharmacoeconomics to identify innovative drugs to be considered for inclusion in the NRDL. This has led to an expansion of the reimbursement of Category B drugs, which increasingly include novel oncology drugs. Reimbursement of Category B drugs requires varying degrees of copayment from patients, depending on their province of residence or type of NHSA insurance scheme enrollment. Inclusion on the NRDL for all listed drugs is subject to renewal every two years.

In this update round, the NHSA has added 23 oncology drugs to the NRDL, including ORPATHYS®. Effective March 1, 2023, medicines included on the NRDL are expected to be made available in pharmacies of major hospitals in China at the negotiated price in accordance with NRDL payment standards, and reimbursement will commence for participants in the NHSA insurance schemes, subject to applicable co-payments by participants.

About Savolitinib

Savolitinib is an oral, potent and highly 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 or other point mutations), gene amplification or protein overexpression.

Savolitinib is marketed in China under the brand name ORPATHYS® for the treatment of patients with NSCLC with MET exon 14 skipping alterations who have progressed following prior systemic therapy or are unable to receive chemotherapy. It is currently under clinical development for multiple tumor types, including lung, kidney and gastric cancers, as a single treatment and in combination with other medicines.

About NSCLC and MET aberrations

Lung cancer is the leading cause of cancer death among men and women, accounting for about one-fifth of all cancer deaths.[1] Lung cancer is broadly split into NSCLC and small cell lung cancer, with 80-85% classified as NSCLC.[2] The majority of NSCLC patients (approximately 75%) are diagnosed with advanced disease, and approximately 10-15% of NSCLC patients in the U.S. and Europe and 30-40% of patients in Asia have EGFRm NSCLC. [3,4,5,6]

MET is a tyrosine kinase receptor that has an essential role in normal cell development.[7] MET overexpression and/or amplification can lead to tumor growth and the metastatic progression of cancer cells, and is the primary mechanism of acquired resistance to EGFR TKIs for metastatic EGFR-mutated NSCLC.[7,8] Approximately 2-3% of NSCLC patients have tumors with MET exon 14 skipping alterations, a targetable mutation in the MET gene.[9] Among patients who experience disease progression post-osimertinib treatment, approximately 15-50% present with MET aberration. [10,11,12,13,14] The prevalence of MET depends on the sample type, detection method and assay cut-off used.[15]

About AstraZeneca and HUTCHMED collaboration

In 2011, AstraZeneca and HUTCHMED entered into a global licensing and collaboration agreement to jointly develop and commercialize savolitinib. Joint development of savolitinib in China is led by HUTCHMED, while AstraZeneca leads development outside of China. HUTCHMED is responsible for the marketing authorization, manufacturing and supply of savolitinib in China. AstraZeneca is responsible for the commercialization of savolitinib in China and worldwide. Sales of savolitinib are recognized by AstraZeneca.

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.

The Company's comprehensive portfolio includes leading lung cancer medicines and the next wave of innovations including TAGRISSO® (osimertinib) and IRESSA® (gefitinib); IMFINZI® (durvalumab) and IMJUDO® (tremelimumab); ENHERTU® (trastuzumab deruxtecan) and datopotamab deruxtecan in collaboration with Daiichi Sankyo; ORPATHYS® (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.

The Company'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, Rare Diseases, 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.

About HUTCHMED

HUTCHMED (Nasdaq/AIM: HCM; HKEX: 13) 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. It has about 5,000 personnel across all its companies, at the center of which is a team of about 1,800 in oncology/immunology. Since inception HUTCHMED has been focused on bringing cancer drug candidates from in-house discovery to patients around the world, with its first three oncology drugs now approved and marketed in China. For more information, please visit: www.hutch-med.com or follow us on LinkedIn.

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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 for the commercialization of savolitinib in China, the potential benefits and further clinical development of savolitinib, its expectations as to whether further studies would meet their primary or secondary endpoints, and its expectations as to the timing of the completion and the release of results from such studies. Forward-looking statements involve risks and uncertainties. Such risks and uncertainties include, among other things, assumptions regarding the commercial acceptance of savolitinib, the impact of the inclusion of savolitinib on the NRDL on sales of the drug and its pricing, clinical trial enrollment rates, timing and availability of subjects meeting a study's inclusion and exclusion criteria, changes to clinical protocols or regulatory requirements, unexpected adverse events or safety issues, the ability of savolitinib to obtain regulatory approval for a targeted indication in different jurisdictions and the sufficiency of funding. In addition, as certain studies rely on the use of osimertinib or durvalumab as combination therapeutics, such risks and uncertainties include assumptions regarding their safety, efficacy, supply and continued regulatory approval and the impact of the COVID-19 pandemic on general economic, regulatory and political conditions. 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, on AIM and with The Stock Exchange of Hong Kong Limited. 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 (as it forms part of retained EU law as defined in the European Union (Withdrawal) Act 2018).

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