Press Release

HUTCHMED Announces NMPA Conditional Approval for TAZVERIK® (tazemetostat) for the Treatment of Relapsed or Refractory Follicular Lymphoma

— First and only EZH2 inhibitor approved by the NMPA —

—HUTCHMED's fourth product, and its first approval in hematological malignancies —

Hong Kong, Shanghai & Florham Park, NJ — Friday, March 21, 2025: HUTCHMED (China) Limited ("HUTCHMED") (Nasdaq/AIM:HCM; HKEX:13) today announces that the New Drug Application ("NDA") for TAZVERIK® (tazemetostat) has been granted conditional approval in China for the treatment of adult patients with relapsed or refractory ("R/R") follicular lymphoma ("FL") with EZH2 mutation who have received at least two prior systemic therapies. This approval follows the priority review status by the National Medical Products Administration ("NMPA") and marks the first nationwide regulatory approval for TAZVERIK® in China.

The conditional approval by the NMPA was supported by results from a multicenter, open-label, Phase II bridging study in China, and clinical studies conducted by Epizyme, Inc. ("Epizyme"), an Ipsen company, outside China. The primary objective of the bridging study is to evaluate the objective response rate ("ORR") of TAZVERIK® for the treatment of patients with R/R FL whose disease harbor EZH2 mutations. The secondary objectives included duration of response ("DoR"), progression-free survival (PFS), and overall survival (OS) of TAZVERIK® for the treatment of R/R FL patients, as well as to evaluate the safety and pharmacokinetics. Additional details can be found at clinicaltrials.gov, using identifier NCT05467943.

"This approval represents a significant advancement in the management of this challenging disease. The majority of FL patients experience multiple relapses over their lifetime, posing substantial treatment difficulties and often leading to poor outcomes," said **Dr Junning Cao of Fudan University Cancer Center** and the lead principal investigator of the bridging study. "TAZVERIK® has demonstrated promising efficacy in patients harboring EZH2 mutation in clinical trials. We are eager to provide this transformational epigenetic therapy to patients in China who have long sought new effective treatment options."

"We are thrilled to be able to bring this innovative EZH2 inhibitor to patients in China. This approval highlights our dedication to addressing unmet medical needs not only through our internal pipeline, but also through partnering," said **Dr Michael Shi, Head of R&D and Chief Medical Officer of HUTCHMED.** "It also marks our first approval in hematological malignancies, unveiling a new chapter for HUTCHMED as we extend our footprint into this disease area. As we move forward, we are dedicated to making this product available to R/R FL patients as soon as possible and will continue striving to make a meaningful impact on the lives of more patients suffering from devastating diseases."

TAZVERIK® is a first-in-class methyltransferase inhibitor of EZH2 developed by Epizyme. It is approved by the US Food and Drug Administration ("FDA") for the treatment of certain patients with R/R FL and certain patients with advanced epithelioid sarcoma ("ES") under the FDA accelerated approval program. It is also approved by the Japan Ministry of Health, Labour and Welfare (MHLW) for certain patients with R/R FL. In 2021, HUTCHMED and Epizyme entered a strategic partnership. HUTCHMED is responsible for the research, development, manufacturing and commercialization of TAZVERIK® in China Mainland, Hong Kong, Macau and Taiwan. Epizyme will be the Marketing Authorization Holder of TAZVERIK® in China.

TAZVERIK® was approved for use in the Hainan Boao Lecheng International Medical Tourism Pilot Zone (Hainan Pilot Zone) in May 2022, under the Clinically Urgently Needed Imported Drugs scheme, for the treatment of certain patients with ES and FL consistent with the label as approved by the FDA. TAZVERIK® was approved in Macau in March 2023 and in Hong Kong in May 2024.

The ongoing SYMPHONY-1 study will serve as the confirmatory trial to validate the clinical benefits of TAZVERIK®. SYMPHONY-1 is an international, multicenter, randomized, double-blind, active-controlled, 3-stage, biomarker-enriched, confirmatory Phase Ib/III study, which is designed to evaluate the safety and efficacy of TAZVERIK® in combination with rituximab and lenalidomide (R^2) in patients with R/R FL after at least one prior line of therapy (NCT04224493). Epizyme is the sponsor of SYMPHONY-1 and HUTCHMED is leading the study in China.

About Follicular Lymphoma

FL is the second most common subtype of non-Hodgkin's lymphoma ("NHL"), making up 20-30% of all NHL. In 2022, there were an estimated 81,000 and 78,000 new cases of NHL in China and the US, respectively.[1,2,3]

About Tazemetostat approval in the United States and Japan

Tazemetostat is a methyltransferase inhibitor indicated in the United States for the treatment of:

- Adults and pediatric patients aged 16 years and older with metastatic or locally advanced ES not eligible for complete resection.
- Adult patients with R/R FL whose tumors are positive for an EZH2 mutation as detected by an FDA-approved test and who have received at least two prior systemic therapies.
- Adult patients with R/R FL who have no satisfactory alternative treatment options.

These indications are approved under accelerated approval by the US FDA based on ORR and DoR. Continued approval for these indications may be contingent upon verification and description of clinical benefit in confirmatory trials.

The most common (≥20%) adverse reactions in patients with ES are pain, fatigue, nausea, decreased appetite, vomiting and constipation. The most common (≥20%) adverse reactions in patients with FL are fatigue, upper respiratory tract infection, musculoskeletal pain, nausea and abdominal pain.

Please see the US Full Prescribing Information for TAZVERIK® (tazemetostat).

TAZVERIK® is approved in Japan with the indication of relapsed or refractory *EZH2* gene mutation-positive FL (only when standard treatment is not applicable).

TAZVERIK® is commercialized by Epizyme in the US and by Eisai in Japan.

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. Since inception it has focused on bringing drug candidates from in-house discovery to patients around the world, with its first three medicines marketed in China, the first of which is also approved around the world including in the US, Europe and Japan. For more information, please visit: www.hutch-med.com or follow us on LinkedIn.

Forward-Looking Statements

This press release contains forward-looking statements within the meaning of the "safe harbor" provisions of the US Private Securities Litigation Reform Act of 1995. These forward-looking statements reflect HUTCHMED's current expectations regarding future events, including its expectations regarding the therapeutic potential of tazemetostat for the treatment of patients with relapsed or refractory follicular lymphoma and the further clinical development of tazemetostat in this and other indications. Forward-looking statements involve risks and uncertainties. Such risks and uncertainties include, among other things, assumptions regarding the sufficiency of clinical data to support NDA approval of tazemetostat for the treatment of patients with follicular lymphoma in China and other jurisdictions, the safety profile of tazemetostat, HUTCHMED's ability to fund, implement and complete its further clinical development and commercialization plans for tazemetostat, and the timing of these events. 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 US Securities and Exchange Commission, The Stock Exchange of Hong Kong Limited and on AIM. HUTCHMED undertakes no obligation to update or revise the information contained in this press release, whether as a result of new information, future events or circumstances or otherwise.

Medical Information

This press release contains information about products that may not be available in all countries, or may be available under different trademarks, for different indications, in different dosages, or in different strengths. Nothing contained herein should be considered a solicitation, promotion or advertisement for any prescription drugs including the ones under development.

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3 The Global Cancer Observatory (GLOBOCAN), Cancer Today | IARC. https://gco.iarc.who.int/today/en/dataviz/bars?cancers=34. Accessed February 17, 2025.