Press Release

HUTCHMED Announces NDA Acceptance in China for Tazemetostat for the Treatment of Relapsed or Refractory Follicular Lymphoma with Priority Review Status

Hong Kong, Shanghai & Florham Park, NJ — Thursday, July 4, 2024: HUTCHMED (China) Limited ("HUTCHMED") (Nasdaq/AIM:HCM; HKEX:13) today announces that the New Drug Application ("NDA") for tazemetostat for the treatment of adult patients with relapsed or refractory ("R/R") follicular lymphoma ("FL") has been accepted for review and granted Priority Review by the China National Medical Products Administration ("NMPA").

Tazemetostat is a first-in-class methyltransferase inhibitor of EZH2 developed by Epizyme, Inc. ("Epizyme"), an Ipsen company. Tazemetostat is approved by the U.S. 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. HUTCHMED entered into a strategic collaboration to research, develop, manufacture and commercialize tazemetostat in China, Hong Kong, Macau and Taiwan.

This China NDA is supported by results from a multicenter, open-label, Phase II bridging study in China, and clinical studies conducted by Epizyme outside China.

Tazemetostat 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. Tazemetostat was approved in the Macau Special Administrative Region ("SAR") in March 2023 and in the Hong Kong SAR in May 2024.

About Follicular Lymphoma

FL is a subtype of non-Hodgkin's lymphoma ("NHL"). FL accounts for approximately 17% of NHL. In 2020, there were an estimated 16,000 and 13,000 new cases of FL in China and the U.S., respectively.[1,2,3]

About Tazemetostat Clinical Development in China

Tazemetostat is a first-in-class methyltransferase inhibitor of EZH2 developed by Epizyme, an Ipsen company. HUTCHMED entered into a strategic collaboration to research, develop, manufacture and commercialize tazemetostat in China, Hong Kong, Macau and Taiwan.

42 patients were enrolled in the Phase II bridging study in China. The primary objective was to evaluate the objective response rate ("ORR") of tazemetostat 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), overall survival (OS), safety and pharmacokinetics of tazemetostat for the treatment of R/R FL patients whose disease do or do not harbor EZH2 mutations. Results of the study will be submitted for presentation at an upcoming medical conference (NCT05467943).

HUTCHMED is participating in Ipsen's SYMPHONY-1 study, leading it in China. This 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 tazemetostat in combination with rituximab and lenalidomide (R^2) in patients with R/R FL after at least one prior line of therapy (NCT04224493).

About Tazemetostat approval in the United States

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 U.S. 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 U.S. 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 a registered trademark of Epizyme Inc., an Ipsen company.

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 approximately 5,000 personnel across all its companies, at the center of which is a team of about 1,800 in oncology/immunology. Since inception it has focused on bringing cancer 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 marketed in the U.S. 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 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 review of a NDA for tazemetostat for the treatment of FL with the NMPA and the timing of such review, therapeutic potential of tazemetostat for the treatment of patients with FL and the further 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 timing and outcome of clinical studies and the sufficiency of clinical data to support NDA approval of tazemetostat for the treatment of patients with FL or other indications in China or other jurisdictions, its potential to gain approvals from regulatory authorities on an expedited basis or at all, 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 U.S. 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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** Name changed from "Panmure Gordon (UK) Limited" to "Panmure Liberum Limited" following completion of its own corporate merger*

REFERENCES

[1] Source: NCCN – https://www.nccn.org
[2] Source: SEER – https://seer.cancer.gov/statfacts/html/follicular.html
[3] Source: GLOBOCAN https://gco.iarc.fr/