

## Press Release

### HUTCHMED Completes Patient Enrollment of a Bridging Study of Tazemetostat in Patients with Relapsed/Refractory Follicular Lymphoma in China

**Hong Kong, Shanghai & Florham Park, NJ — Tuesday, September 12, 2023:** HUTCHMED (China) Limited (“[HUTCHMED](#)”) (Nasdaq/AIM:HCM; HKEX:13) today announces that it has completed patient enrollment of a bridging study of tazemetostat in China.

The bridging study is a multicenter, open-label, Phase II study to evaluate the efficacy, safety and pharmacokinetics of tazemetostat for the treatment of patients with relapsed/refractory follicular lymphoma (“R/R FL”). The primary objective is to evaluate the objective response rate (“ORR”) of tazemetostat for the treatment of patients with R/R FL whose disease harbor EZH2<sup>1</sup> mutations (Cohort 1). The secondary objectives included duration of response (“DoR”), progression-free survival (PFS), and overall survival (OS) of tazemetostat for the treatment of R/R FL patients whose disease do or do not harbor EZH2 mutations (Cohort 2), as well as to evaluate the safety and pharmacokinetics. The lead principal investigator is Dr Junning Cao of Shanghai Fudan University Cancer Center. A total of 42 patients were enrolled. Additional details may be found at [clinicaltrials.gov](https://clinicaltrials.gov), using identifier [NCT05467943](#).

Tazemetostat is a first-in-class methyltransferase inhibitor of EZH2 developed by Epizyme, Inc. (“Epizyme”), an Ipsen company. It is approved by the U.S. Food and Drug Administration (“FDA”) for the treatment of certain patients with advanced epithelioid sarcoma (“ES”) and certain patients with R/R FL under the FDA accelerated approval granted in January and June 2020, respectively. HUTCHMED entered into a strategic collaboration to research, develop, manufacture and commercialize tazemetostat in China, Hong Kong, Macau and Taiwan.

In May 2022, tazemetostat was approved by the Health Commission and Medical Products Administration of Hainan Province of China to be used in the Hainan Boao Lecheng International Medical Tourism Pilot Zone (“Hainan Pilot Zone”), 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.

In March 2023, tazemetostat was approved and launched in Macau. A market authorization application has been under review in Hong Kong since December 2022.

Tazemetostat was included in the Chinese Society of Clinical Oncology (CSCO) guidelines for ES in 2022 and for FL in 2023.

#### About FL and ES

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.<sup>2,3,4</sup>

ES is a rare, slow-growing type of soft tissue cancer. Radical tumor resection is the primary treatment for patients with ES. However, ES is known for its high propensity for locoregional recurrence and distant metastases. The survival of patients with ES is often unsatisfactory with very limited treatment options.<sup>5</sup>

#### About TAZVERIK® (tazemetostat)

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

View the U.S. Full Prescribing Information here:

[https://www.ipсен.com/websites/Ipsen\\_Online/wp-content/uploads/sites/9/2022/11/03075215/TAZ-US-000213\\_TAZVERIK-US-PI-1.pdf](https://www.ipсен.com/websites/Ipsen_Online/wp-content/uploads/sites/9/2022/11/03075215/TAZ-US-000213_TAZVERIK-US-PI-1.pdf)

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

TAZVERIK<sup>®</sup> is a registered trademark of Epizyme Inc., an Ipsen company.

### **About Tazemetostat Clinical Development in China**

HUTCHMED and Ipsen are developing tazemetostat in various hematological and solid tumors in Greater China. We are participating in Ipsen's SYMPHONY-1 (EZH-302) study, leading it in China. We also initiated a Phase II study in combination with our phosphoinositide 3-kinase delta (PI3K $\delta$ ) inhibitor amdizalisib in patients with R/R FL in February 2023. We are generally responsible for funding all clinical trials of tazemetostat in China, including the portion of global trials conducted there.

SYMPHONY-1 (EZH-302) is an international, multicenter, randomized, double-blind, active-controlled, 3-stage, biomarker-enriched, confirmatory Phase 1b/3 study, which is designed to evaluate the safety and efficacy of tazemetostat in combination with rituximab + lenalidomide (R<sup>2</sup>) in patients with R/R FL after at least one prior line of therapy (clinicaltrials.gov identifier: [NCT04224493](https://clinicaltrials.gov/ct2/show/study/NCT04224493)).

China combination study in R/R FL is an open-label, Phase II study in approximately 140 patients to evaluate the safety, tolerability and preliminary anti-tumor efficacy of tazemetostat in combination with amdizalisib in patients with R/R lymphoma. The first patient was dosed in February 2023 (clinicaltrials.gov identifier: [NCT05713110](https://clinicaltrials.gov/ct2/show/study/NCT05713110)).

### **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 oncology drugs now approved and marketed in China. For more information, please visit: [www.hutch-med.com](http://www.hutch-med.com) or follow us on [LinkedIn](https://www.linkedin.com/company/hutchmed).

### **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 therapeutic potential of TAZVERIK<sup>®</sup> for the treatment of patients with ES or FL, the further clinical development of TAZVERIK<sup>®</sup> in this and other indications, risks associated with the use of TAZVERIK<sup>®</sup> in the Hainan Pilot Zone and Macau, including that it could be discontinued in the future for a variety of reasons, the risk that ongoing or future clinical trials conducted by HUTCHMED for TAZVERIK<sup>®</sup> may not meet their primary or secondary endpoints or will warrant meetings with regulatory authorities, submissions for regulatory approval or review by governmental authorities under the accelerated approval process and 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 regulatory approvals, including accelerated approval, to conduct trials or to market products (including to continue offering TAZVERIK<sup>®</sup> in the Hainan Pilot Zone, Macau or elsewhere in China, Hong Kong and Taiwan), its expectations that preclinical studies or earlier clinical studies are predictive of the results of future trials, such as the ongoing confirmatory trials, the safety profile of TAZVERIK<sup>®</sup>, the potential for TAZVERIK<sup>®</sup> to become a new standard of care for ES or FL patients, HUTCHMED's and Epizyme's ability to implement and complete its further clinical development plans for TAZVERIK<sup>®</sup>, the potential commercial launch of TAZVERIK<sup>®</sup> in China and other jurisdictions in the approved indications, the sufficiency of each company's cash resources to fund its foreseeable and unforeseeable operating expenses and capital expenditure requirements, the timing of these events, and the impact of COVID-19 on HUTCHMED's business, results of operations and financial condition and on general economic, regulatory and political conditions. In addition, as certain studies rely on the use of other drug candidates as combination therapeutics with TAZVERIK<sup>®</sup>, such risks and uncertainties include assumptions regarding the safety, efficacy, supply and regulatory approval of such drug candidates. Existing and prospective investors are cautioned not to place undue reliance on these forward-looking statements, which speak only as of the date hereof. HUTCHMED anticipates that subsequent events and developments may cause its views to change; however,*

*HUTCHMED does not undertake any 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. For a 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.*

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<sup>1</sup> EZH2 = Enhancer of Zeste Homolog 2

<sup>2</sup> Source: NCCN<sup>®</sup> – <https://www.nccn.org>

<sup>3</sup> Source: SEER – <https://seer.cancer.gov/statfacts/html/follicular.html>

<sup>4</sup> Source: GLOBOCAN <https://gco.iarc.fr/>

<sup>5</sup> Sobanko JF, Meijer L, Nigra TP. Epithelioid sarcoma: a review and update. J Clin Aesthet Dermatol. 2009;2(5):49-54.