Taiho Oncology Announces Presentation of Data From a U.S. Real-World Study of Oral Decitabine and Cedazuridine

- *Retrospective analysis of patients with myelodysplastic syndromes showed trends in treatment patterns that suggest:*
  - *improved trend persistence with oral decitabine and cedazuridine versus intravenous/subcutaneous hypomethylating agents beyond 6 months*
  - *comparable persistence between oral decitabine and cedazuridine and intravenous/subcutaneous hypomethylating agents at early stages of therapy*

Princeton, N.J., December 10, 2023 – Taiho Oncology, Inc. announced results of a U.S. real-world study of oral decitabine and cedazuridine (DEC-C) in patients with myelodysplastic syndromes (MDS), a rare form of blood cancer. Results of the retrospective real-world analysis of use patterns for hypomethylating agents, suggest oral DEC-C as a treatment option with the potential to reduce patient and caregiver burden, while maintaining patients on therapy. Data from the study were shared during an oral presentation (Abstract #548) at the 65th American Society of Hematology (ASH) Annual Meeting & Exposition.

"For patients with myelodysplastic syndromes, therapy with intravenous or subcutaneous hypomethylating agents has been associated with increased patient burden, which can adversely affect treatment compliance and, subsequently, outcomes," said Amer Zeidan, MBBS, MHS, Associate Professor of Medicine (Hematology), Yale School of Medicine, Interim Chief, Hematologic Malignancies, Yale Cancer Center and Smilow Cancer Hospital, and study investigator. "Previous studies have shown that oral decitabine and cedazuridine provides comparable safety and efficacy to parenteral HMAs,[1,2,3] and what we found in this real-world study is that this oral therapy resulted in a trend for improved persistence as treatment extended beyond the first six months. Based on these results and the potential for reduced treatment burden, oral decitabine and cedazuridine may be a viable alternative to intravenous or subcutaneous HMAs."

In this study of 1,569 patients, 160 received oral DEC-C and 1,409 received intravenous/subcutaneous (IV/SC) HMAs. After matching, there were 158 patients in each treatment cohort. Longitudinal persistence – the accumulation of time from initiation to discontinuation of therapy[4] – was comparable between the matched oral DEC-C and intravenous/subcutaneous HMA cohorts during the first 6 months post-index, with similar proportions receiving the maximum number of treatment cycles (based on a 28-day cycle) at each month following index (73.8% vs 71.1%, 46.5% vs 48.7% and 28.6% vs 24.8%, for 2, 4 and 6 months, respectively). However, a trend toward improved persistence with oral DEC-C versus intravenous/subcutaneous HMAs was observed in patients receiving treatment beyond 6 months (25.0% vs 17.0%, 18.5% vs 9.0% and 11.4% vs 7.6% for 8, 10 and 12 months, respectively). Mean time to discontinuation of treatment was numerically higher for the oral DEC-C users compared with the IV/SC HMA group (87.7 vs 82.0 days); however, the differences were not statistically significant.

"For many patients living with MDS, the potential for additional costs and time associated with travel for regular infusions can be a significant burden during a stressful time in their lives," said Tehseen Salimi, MD, MHA, Senior Vice President Medical Affairs, Taiho Oncology. "Our goal with this study was to

measure the real-world impact of oral therapy. As a leader in the development of orally administered anti-cancer agents, Taiho Oncology is pleased to see how outcomes of this real-world study show some of the potential benefits of an oral therapy in myelodysplastic syndromes."

About the Study
This study was a retrospective analysis using the U.S. Cerner Enviza claims database; medical and prescription claims data for patients were linked to mortality data from Datavant. Adults aged ≥18 years, who were diagnosed with MDS and who had ≥1 claim for an HMA (oral DEC-C or IV/SC HMA) were included. Patients had variable follow-up after the index date and were followed until end of enrollment, death or end of study. Longitudinal persistence was assessed according to the number of cycles of therapy received during follow-up, where a cycle was defined as either 3-10 days of administration of index intravenous/subcutaneous HMA or one claim for oral DEC-C within a 28-day cycle.

About Myelodysplastic Syndromes
Myelodysplastic syndromes are a heterogeneous group of hematopoietic stem cell disorders characterized by dysplastic changes in myeloid, erythroid, and megakaryocytic progenitor cells, and associated with cytopenias affecting one or more of the three lineages. In the U.S., approximately 20,000 cases of MDS are reported every year,[5] with an overall age-adjusted incidence rate of 4.0 cases per 100,000 population.[6] MDS may progress into acute myeloid leukemia (AML) in approximately 30-40% of patients.[7,8] The prognosis for MDS patients is poor; patients die from complications associated with cytopenias (infections and bleeding) or from transformation to AML.

About Taiho Oncology, Inc.
The mission of Taiho Oncology, Inc. is to improve the lives of patients with cancer, their families and their caregivers. The company specializes in the development and commercialization of orally administered anti-cancer agents for various tumor types. Taiho Oncology has a robust pipeline of small molecule clinical candidates targeting solid tumor and hematological malignancies, with additional candidates in pre-clinical development. Taiho Oncology is a subsidiary of Taiho Pharmaceutical Co., Ltd. which is part of Otsuka Holdings Co., Ltd. Taiho Oncology is headquartered in Princeton, New Jersey and oversees its parent company's European and Canadian operations, which are located in Zug, Switzerland and Oakville, Ontario, Canada.

For more information, visit https://www.taihooncology.com/, and follow us on LinkedIn and Twitter.

Amer Zeidan is a paid consultant to Taiho Oncology; he is not paid for work with the media.

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Taiho Oncology Contact:
Judy Kay Moore
(574) 526-2369
jumoore@taihooncology.com

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