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July 7<sup>th</sup>, 2015

**NCCN Guidelines Panel: Bladder Cancer**

On behalf of Eisai Inc., I respectfully request the NCCN Bladder Cancer Guidelines Panel to review the enclosed data for inclusion of Halaven<sup>®</sup> (eribulin mesylate) for the treatment of advanced urothelial cancer.

Specific Changes: Inclusion of eribulin as a treatment option for patients with advanced urothelial cancer.

FDA Clearance: Halaven<sup>®</sup> (eribulin mesylate) is indicated for the treatment of patients with metastatic breast cancer who have previously received at least two chemotherapy regimens for metastatic disease. Prior therapy should have included an anthracycline and a taxane in either the adjuvant or metastatic setting. The FDA has not approved eribulin for the treatment of advanced urothelial cancer.

Rationale: The activity of eribulin in patients with advanced urothelial cancer was demonstrated in a Phase II study. Patients in this study had a calculated CrCl  $\geq 20$  mL/min, and were treated in 3 cohorts of first line, or 2<sup>nd</sup> line with or without tubulin exposure. In each cohort, a response rate of  $>20\%$  was considered promising. Secondary endpoints included progression free survival and overall survival. Eribulin achieved a response rate of 32% in the overall population (n=150). The progression free survival and overall survival with eribulin were 4.1 months and 9.6 months, respectively. Eribulin exceeded the prespecified benchmark in all strata in patients with advanced urothelial cancer. The most common adverse reactions were neutropenia and anemia.

The following literature is submitted in support of this proposed change. We would like to acknowledge the contributions of NCCN panel members who are also co-authors or co-contributors of some of these publications.

1. Halaven<sup>®</sup> (eribulin mesylate) Full Prescribing Information. Eisai Inc., 12/2014.
2. Quinn DI, Ruel N, Twardowski P, et al. Eribulin in advanced urothelial cancer (AUC) patients (pts): a California Cancer Consortium trial – NCI/CTEP 7435. J Clin Oncol 33, 2015 (suppl;abstr 4504). Oral presentation presented at the American Society of Clinical Oncology (ASCO) Annual Meeting, May 29-June 2, 2015; Chicago, IL.

Sincerely,

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