NCCN Guidelines Panel: Kidney Cancer

On behalf of Eisai Inc., I respectfully request the NCCN Kidney Cancer Panel to review the enclosed data for Lenvima® (lenvatinib) capsules in combination with Afinitor® (everolimus) tablets for the treatment of non-clear cell renal cell carcinoma.

Specific Changes: Recommend Lenvatinib + everolimus as “other recommended regimens” for treatment of non-clear cell renal cell carcinoma (nccRCC) (changed from “useful under certain circumstances”).

FDA Clearance: On May 13, 2016, the Food and Drug Administration (FDA) approved Lenvima (lenvatinib) capsules in combination with Afinitor (everolimus) tablets for the treatment of patients with advanced renal cell carcinoma following one prior antiangiogenic therapy. Please refer to the enclosed prescribing information for a complete list of FDA-approved indications for Lenvima and safety information.1

Rationale: A prospective, phase 2, single-arm, multicenter study evaluating the safety and efficacy of lenvatinib + everolimus demonstrated activity of the combination as first-line treatment in 31 patients with unresectable advanced or metastatic nccRCC. Patients who had histologically confirmed nccRCC and no prior chemotherapy for advanced disease were treated with lenvatinib + everolimus and achieved an overall objective response rate (ORR) of 25.8% (95% CI, 11.9-44.6) by both investigator assessment and independent imaging review (IIR). When stratified by histology, ORR was 15% (95% CI 3.2 – 37.9) in the papillary group, 44.4% (95% CI 13.7 – 78.8) in the chromophobe group, and 50% (95% CI 1.3 – 98.7) in those who were unclassified. Median progression-free survival (PFS) was 9.23 months (95% CI, 5.49 – not estimable [NE]) by investigator assessment and 5.62 months (95% CI, 3.48 – NE) by IIR. Median overall survival was 15.64 months (95% CI, 9.23 – NE). The safety profile observed in this study was similar to the established profile of the study-drug combination,2 with no new safety signals. The most common treatment-emergent adverse events (≥10%) in the study were fatigue, diarrhea, decreased appetite, nausea, vomiting, stomatitis, and weight decrease.3

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.
References


Sincerely,

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