NCCN Guidelines Panel: Uterine Neoplasms

On behalf of Eisai Inc., I respectfully request the NCCN Uterine Neoplasms Panel to review and consider the enclosed data for Lenvima® (lenvatinib) capsules in combination with pembrolizumab, for the treatment of patients with endometrial carcinoma that has progressed following prior systemic therapy and that is not microsatellite instability high (MSI-H) or mismatch repair deficient (dMMR).

Specific Changes: Inclusion of lenvatinib in combination with pembrolizumab for the treatment of patients with endometrial carcinoma that has progressed following prior systemic therapy and that is not microsatellite instability high (MSI-H) or mismatch repair deficient (dMMR).

FDA Clearance: The FDA granted breakthrough therapy designation to the investigational combination of lenvatinib and pembrolizumab for the potential treatment of advanced and/or metastatic non-MSI-H/proficient mismatch repair (pMMR) endometrial carcinoma whose disease progressed following at least one prior systemic therapy. Please refer to the enclosed lenvatinib prescribing information for the FDA-approved indications and safety information.

Rationale: The results of an interim analysis (N=53) of a multicenter, open-label, single-arm, phase 2 trial demonstrated the anti-tumor activity of lenvatinib in combination with pembrolizumab in patients with advanced endometrial carcinoma (unselected for microsatellite instability or PD-L1) that has progressed following prior systemic therapy. A total of 21 (39.6% [95% CI: 26.5-54.0]) patients had an objective response at week 24 as assessed by investigators according to irRECIST in the per-protocol population. When assessed by independent imaging review, 24 (45.3% [95% CI: 31.6-59.6]) patients had an objective response at 24 weeks. The most common any-grade treatment-related adverse events were hypertension (58%), fatigue (55%), diarrhea (51%), and hypothyroidism (47%). Serious treatment-related AEs occurred in 30% of patients, including one treatment-related death of intracranial hemorrhage.

The following literature is submitted in support of the proposed change. The results of the final analysis will be published in a peer-reviewed journal. We would like to acknowledge the contributions of NCCN panel members who are also co-authors or co-contributors of this publication.

References


Sincerely,

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