

Keytruda combo gets accelerated approval

December 2019—The Food and Drug Administration granted accelerated approval to the combination of pembrolizumab (Keytruda, Merck) plus lenvatinib (Lenvima, Eisai) for the treatment of patients with advanced endometrial carcinoma that is not microsatellite instability high or mismatch repair deficient and who have disease progression following prior systemic therapy but are not candidates for curative surgery or radiation.

Efficacy was investigated in Study 111/KEYNOTE-146, a single-arm, multicenter, open-label, multicohort trial that enrolled 108 patients with metastatic endometrial carcinoma that had progressed following at least one prior systemic therapy in any setting. Patients were treated with lenvatinib 20 mg orally once daily in combination with pembrolizumab 200 mg administered intravenously every three weeks until unacceptable toxicity or disease progression. Among the 108 patients, 94 had tumors that were not MSI-H or dMMR, 11 had tumors that were MSI-H or dMMR, and in three patients the tumor MSI-H or dMMR status was not known. Tumor MSI status was determined using a polymerase chain reaction test. Tumor MMR status was determined using an immunohistochemistry test.

[Merck](#), 908-740-4000