FDA Approves Keytruda for PD-L1 Positive Advanced Cervical Cancer

Immunotherapy receives accelerate approval for women whose cancer progresses or relapses after chemotherapy.

June 12, 2018 By Food and Drug Administration (FDA)

FDA approves pembrolizumab for advanced cervical cancer with disease progression during or after chemotherapy

On June 12, 2018, the Food and Drug Administration approved pembrolizumab (Keytruda, Merck and Co. Inc.) for patients with recurrent or metastatic cervical cancer with disease progression on or after chemotherapy whose tumors express PD-L1 (CPS ≥1) as determined by an FDA-approved test.

Pembrolizumab was investigated in 98 patients with recurrent or metastatic cervical cancer enrolled in a single cohort of KEYNOTE 158 (NCT02628067), a multicenter, non-randomized, open-label, multi-cohort trial. Patients were treated with pembrolizumab intravenously at a dose of 200 mg every 3 weeks until unacceptable toxicity or documented disease progression. Among the 98 patients, approval was based on 77 (79%) patients who had tumors that expressed PD-L1 with a CPS ≥1 and who had received at least one line of chemotherapy for metastatic disease. PD-L1 status was determined using the PD-L1 IHC 22C3 pharmDx Kit.

The major efficacy outcomes were objective response rate (ORR) according to RECIST 1.1 as assessed by blinded independent central review, and response duration. With a median follow-up time of 11.7 months, the ORR in 77 patients was 14.3% (95% CI: 7.4, 24.1), including 2.6% complete responses and 11.7% partial responses. The estimated median response duration based on 11 patients with a response by independent review was not reached (range 4.1, 18.6+ months); 91% had a response duration of greater than or equal to 6 months. No responses were observed in patients whose tumors did not have PD-L1 expression (CPS <1).

The most common adverse reactions in at least 10% of patients with cervical cancer enrolled in KEYNOTE-158 were fatigue, pain, pyrexia, peripheral edema, musculoskeletal pain, diarrhea/colitis, abdominal pain, nausea, vomiting, constipation, decreased appetite, hemorrhage, UTI, infections, rash, hypothyroidism, headache, and dyspnea. Pembrolizumab was discontinued due to adverse reactions in 8% of patients. Serious adverse reactions occurred in 39% of patients. The most frequent serious adverse reactions reported included anemia (7%), fistula (4.1%), hemorrhage

(4.1%), and infections (except UTIs) (4.1%).

The recommended pembrolizumab dose for treatment of cervical cancer is 200 mg every 3 weeks.

View full prescribing information for Keytruda.

FDA granted this application priority review. This indication is approved under accelerated approval based on tumor response rate and durability of response. Continued approval for this indication may be contingent upon verification and description of clinical benefit in the confirmatory trials. A description of FDA expedited programs is in the Guidance for Industry: Expedited Programs for Serious Conditions-Drugs and Biologics.

Healthcare professionals should report all serious adverse events suspected to be associated with the use of any medicine and device to FDA's MedWatch Reporting System or by calling 1-800-FDA-1088.

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