New Drug Approvals

Generic Name (Trade Nameâ€"Company)

October 1, 2018

Cemiplimab-rwlc

(Libtayo—Regeneron Pharmaceuticals)

FDA approves first treatment for advanced form of the second most common skin cancer

Uses/Notes

FDA approved cemiplimab-rwlc injection for I.V. use for the treatment of patients with metastatic cutaneous squamous cell carcinoma (CSCC) or locally advanced CSCC who are not candidates for curative surgery or curative radiation. This is the first FDA approval of a drug specifically for advanced CSCC.

By blocking the PD-1 pathway, cemiplimab-rwlc may help the body's immune system fight the cancer cells.

Safety and efficacy of cemiplimab-rwlc was studied in two open-label clinical trials. Results showed that 47.2% percent of all patients treated with the agent had their tumors shrink or disappear. The majority of these patients had ongoing responses at the time of data analysis.

Common adverse effects of cemiplimab-rwlc include fatigue, rash, and diarrhea. The agent must be dispensed with a patient Medication Guide that describes uses of the drug and its serious warnings.

Serious adverse reactions include the risk of immune-mediated adverse reactions such as pneumonitis, colitis, hepatitis, endocrinopathies, and dermatologic and kidney problems. Patients should also be monitored for infusion-related reactions.

Because the agent can cause harm to a developing fetus, women should be advised of the potential risk to the fetus and to use effective contraception.

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