FDA Approves Libtayo for Basal Cell Carcinoma

About a quarter of patients with advanced skin cancer experienced tumor shrinkage in a clinical trial.

February 11, 2021 By Food and Drug Administration (FDA)

FDA approves cemiplimab-rwlc for locally advanced and metastatic basal cell carcinoma

On February 9, 2021, the Food and Drug Administration granted regular approval to cemiplimab-rwlc (Libtayo, Regeneron Pharmaceuticals, Inc.) for patients with locally advanced basal cell carcinoma (laBCC) previously treated with a hedgehog pathway inhibitor (HHI) or for whom a HHI is not appropriate and granted accelerated approval to cemiplimab-rwlc for patients with metastatic BCC (mBCC) previously treated with a HHI or for whom a HHI is not appropriate.

Efficacy was evaluated in Study 1620 (NCT03132636), an ongoing open-label, multi-center, non-randomized trial in patients with advanced BCC (laBCC or mBCC) who had progressed on HHI therapy, had not had an objective response after 9 months on HHI therapy, or were intolerant of prior HHI therapy. Eligibility required that laBCC patients were not candidates for curative surgery or curative RT, per multidisciplinary assessment. All patients received cemiplimab-rwlc 350 mg every 3 weeks for up to 93 weeks until disease progression, unacceptable toxicity, or completion of planned treatment.

The main efficacy outcome measures were confirmed objective response rate (ORR) and duration of response (DOR) as assessed by independent central review. For patients without externally visible target lesions (mBCC), confirmed ORR was assessed according to RECIST 1.1. A composite response assessment incorporating clinical response criteria using digital medical photography together with RECIST 1.1, was used for those with externally visible target lesions (laBCC and mBCC).

Among 84 patients with laBCC, the confirmed ORR was 29% (95% CI: 19, 40) with a median DOR not reached (range: 2.1 to 21.4+ months) and 79% of responders maintaining their response for at least 6 months. Among 28 patients with mBCC, the confirmed ORR was 21% (95% CI: 8, 41) with a median DOR not reached (range: 9 to 23.0+ months), and all responders maintaining their responses for at least 6 months.

Severe adverse reactions are immune-mediated adverse reactions (e.g. pneumonitis, hepatitis,

colitis, adrenal insufficiency, hypo- and hyperthyroidism, diabetes mellitus and nephritis) and infusion reactions. The most common adverse reactions (incidence ≥ 20%) were fatigue, musculoskeletal pain, diarrhea, rash, and pruritis.

The recommended dosage of cemiplimab-rwlc is 350 mg as an intravenous infusion over 30 minutes every 3 weeks until disease progression or unacceptable toxicity.

View full prescribing information for Libtayo.

This review used the Assessment Aid, a voluntary submission from the applicant to facilitate the FDA's assessment.

This application was granted priority review. 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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