Generic Name:
Vismodegib
Trade Name:
Erivedge
Company:
Genentech
Notes:

FDA approved vismodegib today under priority review for the treatment of adults with basal cell carcinoma (BCC) that has spread to other parts of the body, that has come back after surgery, or that their health care provider decides cannot be treated with surgery or radiation, according to a Genentech news release. Vismodegib is a once-daily oral capsule that selectively inhibits abnormal signaling in the hedgehog pathway, an underlying molecular driver of BCC.

Approval was based on data from an international, single-arm, multicenter, two-cohort, open-label, Phase II study that enrolled 104 patients with advanced BCC, including locally advanced BCC (n = 71) and metastatic BCC (n = 33). Among the 96 evaluable patients, use of vismodegib resulted in an objective response rate in 43% of patients with locally advanced BCC and 30% of patients with metastatic BCC. Median duration of response was 7.6 months.

Vismodegib was approved with a boxed warning alerting patients and health professionals of the potential risk of death or severe birth defects. The most common adverse events with vismodegib therapy included muscle spasms, hair loss, change in how things taste or loss of taste, weight loss, tiredness, nausea, diarrhea, decreased appetite, constipation, vomiting, and joint aches. Vismodegib will be available within 1 to 2 weeks of approval and will be distributed through specialty pharmacies.

Additional information about this new therapy can be obtained via Erivedge Access Solutions or by calling 888-249-4918.

Medication Monitor Categories:
New Drug Approvals
Use:

Treatment of adults with advanced basal cell carcinoma