Generic Name:
Cetuximab
Trade Name:
Erbitux
Company:
Bristol-Myers Squibb, Lilly
Notes:

Cetuximab is now approved for the treatment of metastatic head and neck cancer in combination with other chemotherapy, according to an FDA news release. The decision was based on data from a multicenter study conducted in 442 patients with inoperable or widespread disease in which patients were randomized to cetuximab plus chemotherapy (cisplatin or carboplatin and 5-fluorouracil) or chemotherapy only.

The addition of cetuximab to chemotherapy was associated with significantly longer median overall survival times, 10.1 months in the group that received chemotherapy plus cetuximab versus 7.4 months in the chemotherapy-only group. In addition, use of cetuximab prolonged the median progression-free survival time from 3.3 to 5.6 months and increased the response rate from 20% to 36%.

The most common grade 3 or 4 adverse events in both groups were anemia, neutropenia, and thrombocytopenia. Sepsis occurred in 9 patients in the cetuximab group and 1 patient in the chemotherapy-only group.

Cetuximab was previously approved by FDA for certain types of colon cancer and for nonmetastatic head and neck cancer in combination with radiation therapy or as a single agent following standard treatment.

Medication Monitor Categories:
Supplemental Approvals
Use:

Treatment of metastatic head and neck cancer