On behalf of Genentech, I respectfully request the NCCN Non-Melanoma Skin Cancers Guideline Panel to review the enclosed data for Erivedge™ (vismodegib) capsule for the treatment of adults with metastatic basal cell carcinoma (mBCC) or with locally advanced basal cell carcinoma (laBCC) that has recurred following surgery or who are not candidates for surgery, and who are not candidates for radiation.

Specific Changes: Consider updating the NCCN Guidelines for Basal Cell Carcinoma with the available data on the use of Erivedge for the treatment of adults with mBCC or with laBCC that has recurred following surgery or who are not candidates for surgery, and who are not candidates for radiation.

FDA Clearance: On January 30, 2012, Genentech, a member of the Roche Group, received FDA approval for Erivedge capsule for treatment of adults with mBCC, or with laBCC that has recurred following surgery or who are not candidates for surgery, and who are not candidates for radiation. Please refer to the enclosed Erivedge prescribing information for the full FDA-approved indication and safety information.

Rationale: The FDA approval of Erivedge is based on results from the pivotal study, ERIVANCE BCC (SHH4476g), in patients with histologically-confirmed, radiographically measureable mBCC or patients with laBCC in which lesions had recurred after radiotherapy, unless radiotherapy was contraindicated or inappropriate, and where the lesions were either unresectable or surgical resection would result in substantial deformity. ERIVANCE BCC is an international, single-arm, multicenter, two-cohort, open-label Phase II study evaluating the efficacy and safety of Erivedge in patients with mBCC or laBCC. Erivedge shrank lesions, as measured by objective response rate (ORR) assessed by independent review, the primary endpoint of the study, in 30 percent of patients with mBCC and 43 percent of patients with laBCC. The most common adverse reactions (incidence of ≥ 10%) are muscle spasms, alopecia, dysgeusia, weight loss, fatigue, nausea, diarrhea, decreased appetite, constipation, arthralgias, vomiting, and ageusia.

There is additional data on the use of Erivedge in patients with Basal Cell Nevus Syndrome (Gorlin Syndrome), which is a genetic condition that predisposes patients to multiple basal cell carcinomas.

The following enclosures are included for your review (copyright-paid where applicable):


- Erivedge™ Prescribing Information

Cited References:

1. Erivedge™ Prescribing Information