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November 2016

IMPORTANT DRUG WARNING

Subject: Extension of Pregnancy Prevention Duration for Women of Childbearing Potential and Waiting Periods for Lactation and Blood Donation in Patients Taking ERIVEDGE® (vismodegib) capsule

Dear Health Care Provider,

The purpose of this letter is to inform you of important new safety information for Erivedge, indicated for the treatment of adults with metastatic basal cell carcinoma, or with locally advanced basal cell carcinoma that has recurred following surgery or who are not candidates for surgery, and who are not candidates for radiation.

Serious Risks with Use of Erivedge

- The recommendation for Erivedge contraceptive duration in women of childbearing potential has changed to 24 months after the last dose.
- This new recommendation is based on an updated exposure threshold for teratogenicity of Erivedge.
- The waiting periods post-treatment on lactation (women) and blood donation in patients taking Erivedge are also being modified to 24 months after the last dose, based on the above.
- There is no change in the current contraceptive advice for male patients, which is 3 months.

Additional information about this change is provided in the remainder of this letter.

Prescriber Action

- Counsel patients about the teratogenic risk of Erivedge.
- Counsel women of reproductive potential to use contraception during treatment and for 24 months after the last dose
- Counsel women to not breastfeed during treatment and for 24 months after the last dose.
- Counsel all patients to not donate blood during treatment and for 24 months after the last dose.

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Additional Information on the Serious Risk

Teratogenicity is an important risk for patients using Erivedge. As part of Genentech's commitment to continuously monitor the safety of its products, a re-assessment of the teratogenic threshold for Erivedge was recently conducted. The toxicity findings of another drug in the same class provided additional information that led to the determination of a different exposure threshold for teratogenicity. This change consequently extends the contraception duration guidance to 24 months post last dose. The waiting period for lactation and blood donation is likewise being changed to 24 months.

There is no change in the current contraceptive advice for male patients. However, it is important to recognize that Erivedge is present in semen, and male patients of all ages, who do not follow the pregnancy prevention plan, are at risk to expose women of childbearing potential to Erivedge. Physicians are reminded to educate patients on the teratogenic risk of Erivedge and the Erivedge pregnancy prevention plan.

Reporting Adverse Events

Health care providers should report adverse events suspected to be associated with the use of Erivedge to: Genentech at 1-888-835-2555. Alternatively, this information may be reported to FDA's MedWatch reporting system by phone (1-800-FDA-1088), by facsimile (1-800-FDA-0178), online (https://www.accessdata.fda.gov/scripts/medwatch/) or mailed, using the MedWatch form FDA 3500, to the FDA Medical Products Reporting Program, 5600 Fishers Lane, Rockville, MD 20852-9787. Pregnancies should be reported to Genentech at 1-888-835-2555.

Company Contact

Should you have any questions about the information in this letter or the safe and effective use of Erivedge, please feel free to contact us at: Genentech Medical Information/Communications Department at 1-800-821-8590.

This letter is not intended as a complete description of the benefits and risks related to the use of Erivedge. Please see the accompanying, current Prescribing Information and Medication Guide for a complete discussion of the risks associated with Erivedge. Genentech is working closely with the U.S. Food and Drug Administration (FDA) to update the product label and Medication Guide for Erivedge.

This letter is being sent to you pursuant to requirements set forth in 21 CFR 200.5 by the U.S. Food and Drug Administration (FDA).

Sincerely,

Myriam Mendila, M.D
Head of US Medical Affairs