Costa Rica, October 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 Healthcare Professional,

Roche would like to inform you of the following:

Summary

- The recommendation for Erivedge contraceptive duration in women of childbearing potential has changed from 9 months 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 from 9 months 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 2 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.

Further information on the Safety Concern

Teratogenicity is an important risk for patients using Erivedge. As part of Roche'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.

Roche is working to update the product information as soon as possible.

Erivedge is indicated for the treatment of adult patients with advanced basal cell carcinoma for whom surgery is inappropriate.

Call for reporting

Health care professionals should report any serious adverse events suspected to be associated with the use of Erivedge® to: cac.farmacovigilancia@roche.com.

Company contact point

Should you have any questions regarding the use of Erivedge®, please feel free to contact us at: cac.medical_info@roche.com.

Sincerely,

Medical Department
Roche Servicios S.A.