< Name and Address>

14 December 2016

IMPORTANT SAFETY UPDATE - ERIVEDGE® (vismodegib)

Extension of Pregnancy Prevention Duration for Women of Childbearing Potential and Interval before Blood Donation and Lactation

Dear Doctor,

Roche Products (New Zealand) Limited ("Roche") would like to inform you of updates to the advice regarding pregnancy prevention, blood donation and lactation in patients receiving Erivedge.

Summary of the Safety Update
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 Erivedge teratogenicity .

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. Likewise, the waiting period for lactation and blood donation has been 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 may 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.

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Updated Safety Information in the Erivedge Data Sheet

- Under Contraindications and Precautions, the recommendation for contraceptive duration in women of childbearing potential has changed from 9 months to 24 months after the last dose of Erivedge.
- Under Contraindications and Precautions, the recommended interval before lactation has been extended from 9 to 24 months post-treatment.
- Under Precautions, the recommended interval before blood donation has been extended from 9 to 24 months post-treatment.

The information above has been added to the Erivedge Data Sheet following Medsafe review. Before prescribing, please review the full Erivedge Data Sheet available at www.medsafe.govt.nz

If you have any questions or require additional information regarding the use of Erivedge please contact Roche Medical Information on 0800 276 243 or email auckland.medinfonz@roche.com

Reporting Adverse Events

Roche will continue to monitor the safety of Erivedge through established reporting mechanisms and notify regulatory authorities of any serious adverse events for evaluation.

Please report any suspected adverse events via email to Roche Drug Safety at nz.drugsafety@roche.com. Alternatively, this information may be reported to the Centre for Adverse Reactions Monitoring (CARM) in Dunedin by telephone on (03) 479 7247, by fax on (03) 479 7150, online at https://nzphvc.otago.ac.nz/reporting or by email nzphvc@otago.ac.nz.

Yours sincerely,
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