Contact Information
Address

<Date>

Subject: **Direct Healthcare Professional Communication**

Tarceva® (erlotinib): First line maintenance non-small cell lung cancer (NSCLC) treatment does not demonstrate a benefit in patients whose tumours do not harbour an EGFR-activating mutation

Dear Healthcare Provider,

Roche Products (New Zealand) Limited would like to inform you about an important study result.

Summary

The results of the IUNO study have led to the conclusion that the benefit-risk of Tarceva in first line maintenance treatment of NSCLC patients whose tumours do not harbour an EGFR-activating mutation is no longer favourable.

Further information

The IUNO study is a randomized, double-blind, placebo-controlled, phase 3 study of first-line maintenance Tarceva versus Tarceva at the time of disease progression in patients with advanced NSCLC whose tumours did not harbour an EGFR-activating mutation (exon 19 deletion or exon 21 L858R mutation) and who have not progressed following 4 cycles of platinum-based chemotherapy. Patients were randomized to receive maintenance Tarceva or maintenance placebo followed by chemotherapy/best supportive care or Tarceva upon disease progression, respectively.

Overall survival (OS) was not superior in patients randomized to receive maintenance Tarceva followed by chemotherapy upon progression compared to patients randomized to receive maintenance placebo followed by Tarceva upon progression (HR=1.02, 95% CI, 0.85 to 1.22, p=0.82). In the maintenance phase, patients who received Tarceva did not have superior progression-free survival (PFS) compared with patients who received placebo (HR=0.94, 95% CI, 0.80 to 1.11, p=0.48).

Based on the results of the IUNO study, the benefit-risk of Tarceva is no longer considered favourable for maintenance treatment in patients without an EGFR activating mutation. First line maintenance treatment of patients whose tumours harbour an EGFR activating mutation (exon 19 deletion or exon 21 L858R mutation) is not impacted by these new data.

An application has been submitted to Medsafe to revise the indication to reflect these new data for maintenance therapy in patients with locally advanced or metastatic NSCLC who have not progressed on first-line chemotherapy.

The other indications for the use of Tarceva in the treatment of NSCLC remain unchanged.

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Before prescribing, please review the full Tarceva Data Sheet available at www.medsafe.govt.nz.
If you have any questions or require additional information regarding the use of Tarceva, please contact Roche Medical Information by phone on 0800 276 243 or by email at auckland.medinfonz@roche.com.

Reporting Adverse Events
Roche will continue to monitor the safety of Tarceva through established reporting mechanisms.
Please report any suspected adverse events via email to Roche Drug Safety at nz.drugsafety@roche.com, and to the Centre for Adverse Reactions Monitoring (CARM) in Dunedin by phone (03) 479 7247, by fax on (03) 479 7150, by email to nzphvc@otago.ac.nz or online at https://nzphvc.otago.ac.nz/reporting/

Yours sincerely,

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