Heredia, Costa Rica October 26, 2015

Tarceva® (erlotinib): First line maintenance treatment not demonstrating benefit in patients whose tumors do not harbor an EGFR-activating mutation

Dear Healthcare Provider,

F. Hoffmann-La Roche Ltd. would like to inform you about an important study result.

Summary

- The results of the IUNO study led to the conclusion that the benefit-risk of Tarceva for maintenance treatment of patients with locally advanced or metastatic non-small cell lung cancer (NSCLC) after 4 cycles of standard platinum-based first-line chemotherapy whose tumors do not harbor an EGFR-activating mutation is no longer considered favorable.

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 tumors did not harbor an EGFR-activating mutation (exon 19 deletion or exon 21 L858R mutation) 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

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

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

Company contact point
Should you have any questions regarding the use of Tarceva® (Erlotinib), please feel free to contact us under the below address: cac.medical_info@roche.com.

Yours,
ROCHE SERVICIOS S.A.

Dr. Daniel Álvarez
Medical Director

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