Roche Erlotinib Assessment Group Comments

1. The AG model does not consider the totality of adverse event information available for the interventions compared

We note that when comparing erlotinib and docetaxel the AG have utilised solely the rate of adverse events observed in the TAILOR study. They have not considered the pooled adverse event rates across the multiple trials in which docetaxel has been investigated. It should be noted the adverse event rates reported in TAILOR are considerably lower than those seen in the pooled analysis of AE's shown in table 41.

We believe it is appropriate to consider the totality of evidence on AEs available and not focus solely on the data collected in a single study. There is no reason to believe cytotoxic associated AE rates would differ depending upon EGFR mutation status and so it appears appropriate to utilise AE rates from the pooled analysis.

Applying the pooled AE rates to the AG model would increase the ICER per QALY for docetaxel compared to erlotinib to above £40k – this is a first order issue that could have a significant impact on the decision reached by the Committee and should therefore be carefully and systematically considered using all available data.

It is plausible that the lower AE rates, particularly neutropenia and febrile neutropenia, are a consequence of a lower weekly dose of docetaxel being available in TAILOR. Reduced toxicity is the primary driver behind using the more resource-intensive weekly schedule for docetaxel rather the typical three weekly schedule.

However, the weekly schedule is not regularly used in the UK, and if the AG were to wish to make a comparison against this regimen (and its potential lower toxicity) it would require the docetaxel administration costs in the model to be increased 3-fold.

2. There is an ambiguous description of post-progression therapy in Section 3.2

Section 3.2 states that 33% of patients go on to receive further chemotherapy treatment following disease progression after first line therapy. We believe that this should read; go on to receive active treatment which includes chemotherapy or other systemic anti-cancer drug therapy. Similarly section 3.2.1 states that 25% of PS 0 -1 patients receive second line chemotherapy and 5% - 15% of PS 2 receive second line treatment. We believe that both of these should read second line chemotherapy (for both fit and less fit patients others receive other systemic anti-cancer drug therapy taking the total second-line treatment rate up to about 33%, as above). For those patients that go on to receive a second line active treatment, erlotinib is currently used in 7 out of 10 patients (Kantar Health on behalf of Roche), with docetaxel being prescribed for the remainder.

3. We acknowledge the incorrect valuation of pharmacist time in our submission (p 89)

Updating to the 2012 PSSRU figure increases our base case ICER for erlotinib compared to best supportive care in EGFR unknown patients marginally (by £170).

References

Roche, Data on File RXUKDONF00270, November 2012. Data taken from a Custom Patient Record Research Report on NSCLC, conducted by Kantar Health on behalf of Roche