A REVIEW OF THE COST-EFFECTIVENESS OF NILOTINIB (TASIGNA®) FOR THE TREATMENT OF THE CHRONIC-PHASE OF CHRONIC MYELOID LEUKAEMIA (CML)

National Centre for Pharmacoeconomics

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Summary

1. In January 2008, Novartis Ireland Ltd. submitted an evaluation of the cost-effectiveness of nilotinib, a new orally active aminopyrimidine derivative tyrosine kinase inhibitor for the treatment of the chronic-phase of chronic myeloid leukaemia (CML) in patients who have failed imatinib (Glivec) due to resistance or intolerance.

2. The comparator chosen for the cost-utility Markov model was dasatinib, the current second-line treatment. Evidence for efficacy of both agents was derived from Phase II non-comparative studies, as no head-to-head comparative or randomised controlled trials have been undertaken to date. Major cyotogenetic response (MCyR) data were used as an indirect measure of survival for patients commenced on therapy.

3. The base case analysis provided an incremental cost effectiveness ratio (ICER) of €77,463/QALY for nilotinib when compared with dasatinib. This ICER exceeds the current threshold of €45,000/QALY. A limited univariate sensitivity analysis confirmed the ICER was sensitive to the price of nilotinib. Reducing the price of nilotinib from €184.65/day to €173.11/day resulted in a decrease in the ICER from €77,463/QALY to €49,884/QALY. Reducing the time horizon from 100 years rendered the intervention less cost-effective. A 5 year time horizon resulted in an ICER of €206,196/QALY.

4. The cost-effectiveness of nilotinib as compared to dasatinib in patients who are resistant to imatinib has not been demonstrated. The results of this cost effectiveness analysis suggest that nilotinib could be reserved at this point in time for patients with chronic-phase CML who fail second-line TKI therapy with dasatinib.