Pharmacoeconomic evaluation of Ipilimumab (Yervoy®) for the treatment of advanced (unresectable or metastatic) melanoma in adult patients who have received prior therapy.



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- An economic evaluation of ipilimumab (Yervoy®) for the treatment of advanced (unresectable or metastatic) melanoma in adult patients who received prior therapy was submitted to the National Centre for Pharmacoeconomics (NCPE) by BMS Pharmaceuticals on the 29<sup>th</sup> July 2011.
- 2. Ipilimumab is a monoclonal antibody that blocks cyctotoxic T-lymphocyte associated antigen 4 (CTLA-4), a negative regulator of T cells, thereby augmenting T-cell activation and proliferation. The economic evaluation was in the form of a cost utility analysis and the perspective was that of the Irish Health Services Executive (HSE).
- 3. The cost effectiveness of ipilimumab was demonstrated using a Markov decision analysis model programmed in Microsoft Excel with three primary health states i.e. progression free survival, post progression and death. All patients enter the model in the progression free health state and exit the model at death or the 10 year time horizon. The clinical outcome and utility data incorporated into the model was derived from the study by Hodi et al 2010. Costs and consequences were discounted at an annual rate of 4%.
- 4. In the basecase analysis, the incremental cost per quality adjusted life year (QALY) gained with ipilimumab versus best supportive care was estimated at €147,899/QALY. The incremental cost per life year gained (LYG) was €92,443/LYG.
- 5. A comprehensive sensitivity analysis demonstrated that important factors influencing the cost effectiveness of ipilimumab included methods used to estimate health state utilities, methods used for extrapolation of progression free survival and overall survival, the time horizon and the price of ipilimumab. The probabilistic sensitivity analysis indicated that the probability of ipilimumab being cost effective over a willingness to pay range of €20,000/QALY to €45,000/QALY was 0%.

- 6. The submission included a budget impact assessment for ipilimumab therapy based on a cost per dose exceeding €20,000 and an average cost per treatment (four cycles) exceeding €35,000. Depending on the scenario used, the gross budget impact of ipilimumab therapy ranged from €4.8million €7.4 million in 2012 increasing to €5.3 million €8.2 million in 2016.
- We believe the Company has failed to demonstrate the cost-effectiveness of ipilimumab for the treatment of advanced melanoma in adult patients who received prior therapy. We cannot recommend reimbursement at the submitted price.