Proffered Papers

compared to younger patients (18–49 years: 9%; 50–59 years, 9%). At 6 months post-enrollment, a greater percentage of patients \geqslant 70 years of age were anemic (54%) compared to patients in the other age groups (range: 44% to 48%) and a greater percentage of these elderly patients had Hb levels < 10.0 g/dL (14%) compared to the other age groups (range: 10% to 11%). Overall, increasing age had a negative effect on WHO performance score at enrollment and during the 6-month survey; patients \geqslant 70 years had consistently lower WHO scores compared to younger patients. The majority of patients (72% overall) did not receive anemia treatment after enrollment. For patients who did receive treatment, more were in the older age groups (60–69 years: 29%; \geqslant 70 years: 31%) compared to younger patients (18–49 years: 25%; 50–59 years, 27%). Patients \geqslant 70 years received the most epoetin (16%) compared to other age groups (11% to 13%).

Conclusions: Patients of all ages have significant anemia, although elderly patients appear to have more anemia overall with lower Hb levels and worse WHO performance scores. Effective anemia treatment should be administered to cancer patients regardless of age to insure optimal patient management.

1282 POSTER

Economic analysis of aprepitant in patients receiving antiemetic prophylaxis with moderately emetogenic chemotherapy in France – results of a decision-analytic model

J. Pellissier¹, <u>Y. Briand</u>², G. Davies², T. Souchet¹, R. Deuson³. ¹Merck & Co. Inc, Health Economic Statistics, Blue Bell, PA, USA; ²Msd Chibret France, Health Economics And Outcome Research, Paris, France; ³Merck & Co. Inc, Outcomes Research, Whitehouse Station, NJ, USA

Background: Chemotherapy-induced nausea and vomiting (CINV) remains a major adverse effect of cancer chemotherapy. Aprepitant, a NK1 receptor antagonist, represents a new approach to antiemetic therapy. **Objective:** To evaluate the economic implications of treatment with

Objective: To evaluate the economic implications of treatment with aprepitant relative to standard therapy for French patients undergoing moderately emetogenic chemotherapy (MEC)

Methods: A decision analytic model compared a 3 day aprepitant regimen (Day 1: aprepitant 125 mg P.O. in combination with ondansetron 8 mg P.O. twice daily and dexamethasone 12 mg P.O.; Day 2–3: aprepitant 80 mg P.O. once daily) to standard therapy (Day 1: ondansetron 8 mg P.O. twice daily and dexamethasone 20 mg P.O.; Day 2–3: ondansetron 8 mg P.O. twice daily) over a single chemotherapy cycle. The model was based on clinical results and healthcare resource utilization observed in a large clinical trial of aprepitant in MEC. Trial outcomes included complete response (no emesis, no rescue therapy), impact of CINV on daily life, and quality-adjusted life years (QALYs). QALY data were obtained from the literature. French costs were used to cost health care resources: a) hospital costs (http://www.atih.sante.fr/), b) ambulatory fees (http://www.ameli.fr/); and c) drug prices (http://www.gie-gers.fr/).

Sensitivity of results to changes in model parameters was investigated through a series of sensitivity analyses.

Results: In the aprepitant group (n = 429) 51.3% of the patients were complete responders over the entire chemotherapy cycle compared to 42.7% in the standard care group (n = 422). More patients were CINV-free over the entire chemotherapy cycle with aprepitant regimen (54.1%) compared to standard regimen (46.0%). Expected cost difference between aprepitant regimen and standard therapy was *1.07, with 98% of the aprepitant cost offset by savings in 5HT3 drug costs and healthcare resource use. Expected marginal cost-per-QALY-gained with aprepitant was *1,890. Results were robust with respect to all healthcare resource utilization costs, and most sensitive to costs of prophylactic 5HT3s and utilities for CINV health states.

Conclusion: Patients receiving aprepitant-based treatment for MEC had better CINV-related outcomes compared to patients receiving standard regimen with nearly all of the drug cost of aprepitant being offset. An aprepitant-based treatment for prevention of CINV in MEC patients appears to be cost-effective in France.

POSTER

Darbepoetin alfa administered once every 3 weeks (Q3W) is effective for treating anaemia in patients receiving multicycle chemotherapy: results of a randomised, double-blind, active-controlled trial

J. Canon¹, J. Vansteenkiste², G. Bodoky³, M.V. Mateos⁴, L. Bastit⁵, I. Ferreira⁶, R. Amado⁶. ¹ Centre Hospitalier Notre Dame et Reine Fabiola, Oncology-Hematology CHNDRF, Charleroii, Belgium; ² University Hospital Gasthuisberg, Leuven, Belgium; ³ Szt. László Hospital, Budapest, Hungary; ⁴ University of Salamanca Hospital Clinic, Salamanca, Spain; ⁵ Centre Fréderic Joliot, Rouen, France; ⁶ Amgen Inc, Thousand Oaks, Calif, USA

Background: Darbepoetin alfa (Aranesp®; DA) is licensed in Europe for the treatment of chemotherapy-induced anaemia using either once weekly (QW) or Q3W administration. The Q3W schedule is convenient because it can be synchronized with many chemotherapy regimens, resulting in fewer visits and reduced burden to patients (pts). This study evaluated the comparability (non-inferiority) of a fixed starting dose of 500 mcg Q3W with 2.25mcg/kg QW DA, with respect to efficacy and safety.

Methods: This was a randomised, double-blind, double-dummy, active-controlled phase 3 study in 110 centres across Europe. Eligible subjects were \geq 18 years of age, anaemic (haemoglobin [Hb] < 11 g/dL), and diagnosed with a non-myeloid malignancy with \geq 12 weeks of planned chemotherapy. Pts were randomised 1:1 to Q3W or QW DA for 15 weeks. The primary endpoint was incidence of red blood cell transfusions from week 5 to end of treatment phase. Non-inferiority was determined if the 95% confidence interval (Cl) of the difference in transfusions between groups did not exceed a pre-specified margin based on previous placebo-controlled studies of DA 2.25 mcg/kg QW. The primary analysis included pts who received \geq 1 dose and who were enrolled in the study until at least day 29. Secondary endpoints included change in Hb and FACT-F, and achievement of Hb \geq 11 g/dL.

Results: 705 pts were randomised; 672 were analysed for the primary endpoint. Demographic characteristics were similar between the 2 treatment groups. Transfusion incidence (95% CI) was 23% (19 to 28) and 30% (25 to 35) for the Q3W and QW groups, respectively (difference: -6.8 percentage points [-13.6 to 0.1]) We observed a similar difference in transfusion requirements between treatment groups after adjusting for stratification factors, and for pts with haematological and solid tumours. The proportion of pts achieving Hb≥11 g/dL was 84% (Q3W) and 77% (QW); pts achieving the dose-withholding limit of Hb ≥ 13 g/dL was 24% (Q3W) and 22% (QW). The safety profile was similar for the 2 treatment groups, with no association between cardiovascular/thromboembolic adverse events and rapid rise in Hb levels or Hb ≥ 13 g/dL. Fifty-seven percent (Q3W) and 58% (QW) of pts had ≥ 3-point increase in FACT-F. In the Q3W arm, the median number of doses was five compared with 14 doses in the QW arm. Conclusions: The Q3W regimen was comparable to the QW regimen since the upper limit of the CI of the transfusion incidence fell substantially below the pre-determined non-inferiority margin. These results demonstrate effective anaemia management with less frequent dosing of DA

1284 POSTER

ECAS, MEWACAS and ACAS: Contrasts and comparisons of three regional, multinational, prospective anemia surveys in cancer patients

P. Gascon¹, T. Seshadri², M. Prince². For ECAS, MEWACAS, and ACAS Investigators (Europe, Middle East/Western Asia, Australia). ¹Hospital Clinic, Servei d'Oncologia Media, Barcelona, Spain; ²Peter MacCallum Centre, Haematology Service, Melbourne, Australia

Background: European Cancer Anaemia Survey (ECAS) was the first survey to evaluate prospectively and objectively the prevalence, incidence, and management of anemia (Ludwig et al, EJC 2004) and define predictive risk factors for anemia (Van Belle et al, Ann in Oncol 2004 abstract) in a large population of cancer patients (pts). Pts (n = 15,367) with solid (78.9%) and hematological malignancies (21.1%) from 24 countries in 824 centers were followed for up to 6 months. Data demonstrate a high prevalence of anemia (67%) in cancer pts, particularly those undergoing chemotherapy (CT) [75%] and with no cancer therapy (40%), with an adverse effect on WHO performance status.

Methods: To facilitate comparable data on anemia from cancer pts in the Middle East/Western Asia (MEWA) region, the MEWA Cancer Anaemia Survey (MEWACAS) was instituted, a prospective, epidemiologic, observational survey conducted in 11 countries, including Cyprus, Egypt, Iran, Israel, Jordan, Kuwait, Lebanon, Libya, Malta, Saudi Arabia, and the United Arab Emirates. Additionally, a similar data collection record form was used in Australia in 24 cancer centres (Seshadri *et al*, *MJA* 2005) for the Australian Cancer Anaemia Survey (ACAS).

Results: Demographics of the three surveys differed slightly (see table below). There were 921 patients enrolled in MEWACAS and 694 pts were