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similar system and believe that our positive experience should encourage more widespread usage.

124

Health-related quality of life impact of idelalisib in patients with relapsed chronic lymphocytic leukemia (CLL): phase 3 results

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Patient-reported outcomes (PROs), including health-related quality of life (HRQL), from randomised clinical trials may be used to inform clinical decision making and reimbursement decisions. Idelalisib (IDELA), an oral inhibitor of PI3Kδ, is highly active in frail, heavily pre-treated patients with CLL as single agent or combined with rituximab (R).The aim of this study was to use PROs to evaluate HRQL among patients with relapsed CLL being treated with idelalisib in Study 116, a double-blind, placebo-controlled phase 3 trial (Furman et al, NEJM, 2014).Patients were randomized to IDELA + rituximab (R) (n = 110) versus placebo + R (n = 110). The 44-item Functional Assessment of Cancer Therapy–Leukaemia (FACT-Leu) scale was used to measure physical (PWB), functional (FWB), social (SWB) and emotional (EWB) well-being and leukaemia-specific concerns (LeuS). The FACT Leu total score is the sum of subscales; Trial outcome index (TOI) is the sum of PWB, FWB and LeuS. Higher scores reflect better HRQL. Repeated measures mixed-effects models assessed change from baseline within and between arms. IDELA+R was superior for OS: HR=0.28 (0.09, 0.86), p = 0.018. In the mixed-effects model analysis, PWB (p = 0.015), FWB (p = 0.014), LeuS (p = 0.001), TOI (p = 0.002), and FACT Leu total (p = 0.006) scores were significantly higher for IDELA+R. EWB/SWB scores did not change significantly over time. In this frail CLL population, IDELA+R had superior efficacy, clinically significant improvements in HRQL, and superior symptom control occurring by 8 weeks compared to R+placebo.

125

Obinutuzumab (GA101) in combination with CHOP (cyclophosphamide, doxorubicin, vincristine and prednisone) or bendamustine for the first-line treatment of follicular non-Hodgkin lymphoma: final results from the maintenance phase of the phase Ib GAUDI study

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The GAUDI study investigated safety and efficacy of induction obinutuzumab (G) plus CHOP (G-CHOP) or bendamustine (G-B) followed by G-maintenance for untreated follicular lymphoma (FL). Maintenance data are reported. Patients with treatment-naïve CD20+ FL received induction G (IV 1000 mg) plus standard CHOP (3-weekly, 6–8 cycles) or B (IV 90 mg/m^2, 4-weekly, 4–6 cycles). Induction responders (complete response [CR]/partial response [PR]) received G-maintenance (3-monthly for 2 years/until disease progression [PD]). Patients completing maintenance were followed for another 2 years/until PD/new anti-lymphoma therapy. Results are presented by induction arm. Overall safety population: G-B: n = 41, G-CHOP: n = 40; baseline characteristics were balanced; median observation time: 32 months. Maintenance safety population: n = 36/arm; most patients completed maintenance (G-B: 81%; G-CHOP: 72%). During 2 years' maintenance, most patients had AEs (G-B: 100%; G-CHOP: 78%). Grade ≥3 AEs (G-B: 44%; G-CHOP: 31%) were mainly infections (G-B: n = 6 [17%; seven AEs]; G-CHOP: n = 5 [14%; five AEs]; four treatment-related [TR] AEs/arm), and cytopenia (G-B only; n = 6 [17%]; 10 AEs [7/10 TRAEs], 5/10 AEs were neutropenia [2/5 TRAEs]). TRAEs during/≤24 hours after an infusion: G-B: n = 1; G-CHOP: n = 2; all grade 1/2. One patient (G-CHOP) died (G-related respiratory tract infection with fatal lactic acidosis). All patients with available data were B-cell depleted (<0.07 × 10^{9}cells/l) at end of treatment (EOT; n = 80) and 6–9 months post-EOT (n = 22); 6/12 patients assessed 9–24 months post-EOT recovered. Median IgG remained within normal range. As some patients converted from PR to CR during maintenance, rates of CR as best overall response increased from induction end to cut-off date (G-B: 37–61%; G-CHOP: 35–70%). Median progression-free survival, not reached (PD: n = 10); 32-month progression-free survival: 92% (G-B), 84% (G-CHOP). These data demonstrate that G-maintenance was well-tolerated following immunochemotherapy induction in FL patients. The phase III GALLIUM trial investigating G-chemotherapy versus rituximab-chemotherapy in untreated indolent non-Hodgkin lymphoma has completed recruitment.