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| **A sequential cohort study comparing KappaMab alone to KappaMab, lenalidomide and low dose dexamethasone in kappa-restricted relapsed/refractory multiple myeloma (AMaRC 01-16)** |
| **Aim**: To establish the clinical benefit rate (CBR) of KappaMab alone (Stage 1) and in combination with lenalidomide and low dose dexamethasone (Stage 2). To evaluate safety and survival (PFS, OS).**Methods**: Investigator initiated, phase IIb, multi-centre, open label sequential cohort study comparing KappaMab alone to KappaMab combined with lenalidomide, dexamethasone in relapsed/refractory kappa-restricted MM, 1-3 prior lines (lenalidomide naive). Stage 1: KappaMab (10mg/kg IV infusion) weekly for 8/52 (induction), then every 4/52 (maintenance). [One cycle: 28d]. Stage 2: KappaMab dosed as per Stage 1 plus lenalidomide (25mg D1-21) and dexamethasone (40mg weekly). In cycle 1 of Stage 2, lenalidomide and dexamethasone commenced 1/52 prior to KappaMab. [Cycle 1 only: 35d]. Treatment continued until toxicity/progression. This is a planned interim analysis of the primary endpoint (CBR). **Results**: 54 of planned 60 patients have commenced treatment; however 40 are included in this analysis (Stage 1=19, Stage 2=21). Median 2 prior lines of therapy. 12 patients remain on study (Stage 1=1, Stage 2=11). 20 have progressed (Stage 1=14, Stage 2=6), 5 have died (Stage 1=2, Stage 2=3). Estimated median potential follow-up was 3.7m in Stage 1, and 4.9m in Stage 2.Stage 1 observed CBR was 5% (1/19, PR=1) compared to 77% in Stage 2 (16/21, VGPR=2, PR=12, MR=2). ORR was 67% for Stage 2.Median PFS for Stage 1 was 3.7m, compared to 6.2m for Stage 2. Median OS for both stages was not reached. 3/19 patients in Stage 1 had infusion reactions (grade 1 and 2), 4/21 patients in Stage 2 (grade 2). **Conclusion**: KappaMab combined with lenalidomide and dexamethasone has higher than expected response rates (ORR 67%, median 2 prior lines): ORR after one prior line in the MM-009/MM-010 trials of lenalidomide, dexamethasone was 66.9%1. This novel immune-oncology combination may represent a promising new therapeutic option. Trial is ongoing.**Reference**1. E Stadtmauer et al. Lenalidomide in combination with dexamethasone at first relapse in comparison with its use as later salvage therapy in relapsed or refractory multiple myeloma. European Journal of Haematology 2009; 82:426-432
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