MOR202 WITH LOW-DOSE DEXAMETHASONE (DEX) OR POMALIDOMIDE/DEX OR LENALIDOMIDE/DEX IN RELAPSED OR REFRACTORY MULTIPLE MYELOMA (RRMM): A PHASE I/IIA, MULTICENTER, DOSE-ESCALATION STUDY

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Background

CD38 is a type II transmembrane glycoprotein expressed by MM cells. MOR202, a human IgG1 CD38 monoclonal antibody, has shown high single-agent activity in preclinical models of MM and synergy in combination with immunomodulatory drugs (IMiDs®), lenalidomide (LEN) and pomalidomide (POM).

Aims

The primary objectives of the study were to evaluate the safety, maximum tolerated dose (MTD)/recommended phase II dose of MOR202 in patients with relapsed or refractory multiple myeloma.

Methods

This is an analysis of a multicenter, dose-escalation phase I/IIa study of MOR202 with data presentation from patient (pt) cohorts treated with clinically relevant doses of MOR202 (2-hour IV infusion; 4, 8 and 16 mg/kg q1w) + Dex (≤40 mg), or at 8 or 16 mg/kg q1w with an IMiD+Dex combination.

Results

As of September 2017, 91 pts had been treated, including 56 in clinically relevant cohorts: 18 received MOR202 + Dex, 17 MOR202 + LEN/Dex and 21 MOR202 + POM/Dex. Pts received a median of 3, 2 and 3 prior treatment lines, respectively. The MTD of MOR202 was not reached. Combinations were generally well tolerated, with grade ≥3 adverse events (AEs) of mainly hematological nature. 2 pts discontinued due to a MOR202-related AE (one patient with a grade 4 thrombocytopenia and one patient with a grade 3 bacterial infection complicated by acute kidney failure). Infusion-related reactions (all grade 1 or 2) were observed in 4/56 (7%) pts. These mainly occurred during the first infusion. In the MOR202 + Dex cohort, 5/18 (28%) pts showed a response: 3 partial responses (PRs) and 2 very good PRs (VGPRs). Responses were also observed in 11/17 (65%, 7 PRs, 3 VGPRs, 1 complete response [CR]) pts in the MOR202 + LEN/Dex cohort and 9/21 (43%, 3 PRs, 4 VGPRs and 2 CRs) in the MOR202 + POM/Dex cohort. Longest response duration was 25 months (MOR202/Dex). Preliminary results indicate preservation of high CD38 levels on MM cells under MOR202 therapy.

Conclusion

2-hour infusions of MOR202 administered at up to 16 mg/kg with Dex or in combination with an IMiD/Dex in heavily pretreated pts with RRMM showed a favorable safety profile, including excellent infusion tolerability. Promising preliminary efficacy and long-lasting tumor control were observed.

Session topic: 14. Myeloma and other monoclonal gammopathies - Clinical

Keyword(s): CD38, Dose escalation, Multiple Myeloma