A Phase I trial of SAR650984, a CD38 monoclonal antibody, in relapsed or refractory multiple myeloma

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18 patients were enrolled in a 2-stage, dose-escalation study. Eligible patients had relapsed or refractory multiple myeloma (RRMM) and had received at least 3 prior lines of therapy. The study objectives were to determine the maximum tolerated dose (MTD), assess clinical and pharmacokinetic correlates of receptor occupancy (%RO) and safety of SAR650984.

Study objectives

- The primary objective was to determine the maximum tolerated dose (MTD).
- Secondary objectives included assessment of safety and tolerability, pharmacokinetics, and preliminary disease responses.

Efficacy

- Median values for baseline and end of treatment were calculated.
- Five patients achieved partial response (PR; Figure 3).
- Two patients achieved clinical benefit (CB; Figure 3).

Safety

- No infusion-related hypersensitivity reactions (HR-SRs) were reported.
- No grade 4 or 5 adverse events (AEs) were reported.
- Grade 3/4 AEs were observed in 1 of 10 patients.
- The most frequent grade 3/4 AEs were anemia (28%), upper respiratory tract infection (23%), and lymphopenia (18%).

Pharmacokinetics

- SAR650984 clearance decreased with increasing dose (Figure 4, left panel).
- SAR650984 distribution volume decreased with increasing dose (Figure 4, right panel).

Conclusions

- Preliminary results of a Phase Ib study of SAR650984 in combination with lenalidomide and dexamethasone are reported in abstract 6552.

References


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Data points and geometric means are for q2W dosing (filled circles) and q1W dosing (open circles).

Figure 3. Clinical response summary

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