

INTRODUCTION

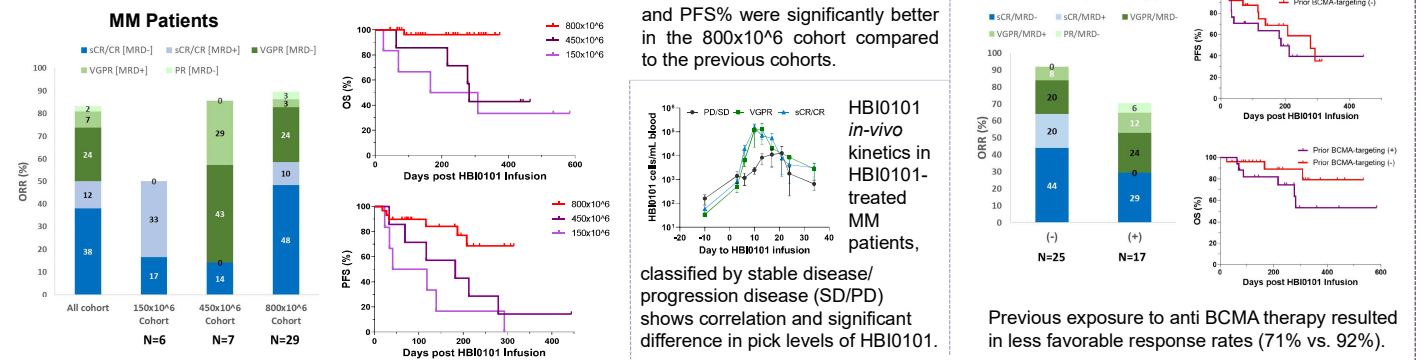
Anti-BCMA chimeric antigen receptor (CAR) T-cells for the treatment of multiple myeloma (MM) have proven safe and efficacious. Recently, two commercial products (i.e., ABECMA™ and CARVYKTI™) have been approved by the FDA and EMA agencies, auguring a rapid expansion of these "living-drugs" to the market. However, this is not the case yet, since access to this modality of treatment remains very limited. The lack of production slots, manufacturing costs, and logistical issues are major drawbacks of this therapy and present significant obstacles to meeting the growing demand.

Point-of-care CART manufacture and delivery is an especially attractive approach for boosting the supply of CART products. In Israel, about 500 cases of myeloma are newly diagnosed every year, and about 100 cases will become candidates for CART therapy, as third-line therapy. At Hadassah Medical Center (HMC) we have developed a new anti-BCMA CAR (HB10101) for the treatment of MM and light chain amyloidosis (AL). CART products are manufactured and delivered to patients in-house, considerably shortening the "vein-to-vein" waiting time, which is critical especially for rapidly deteriorating patients.

RESULTS

The results of the phase Ia/b study (NCT04720313), exploring the safety and efficacy effects in 47 patients (42 MM- and 5 AL- patients) at escalating doses ranging from 150- to 800x10⁶ CAR+ cells presented here. As of data cutoff at 23/10/2022, the median follow-up (mFU) was 146 days (range, 18-314), with a median progression-free survival (mPFS) and overall survival (mOS) not reached yet at the higher dose.

The overall response rate for all cohorts was 83%, with a 90% response rate in the 800x10⁶ cohort. Both OS⁺ and PFS⁺ were significantly better in the 800x10⁶ cohort compared to the previous cohorts.



CONCLUSION

HB10101 CART product exhibits comparable safety and efficacy properties as the commercial anti-BCMA CART products reported in the literature (ABECMA™), with a clinically manageable safety profile and promising in-vivo efficacy. Hadassah Medical Center's experience testifies of the feasibility of a decentralized approach for point-of-care CART manufacture to supply the local demand.

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