

Long-term follow-up of ARI0002h (cesnicabtagene autoleucel), an academic point-of-care B-cell maturation antigen (BCMA)-directed chimeric antigen receptor (CAR) T-cell strategy: Activity and safety after fractionated initial therapy and booster dose in 60 patients with relapsed/refractory multiple myeloma (RRMM)

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Background:

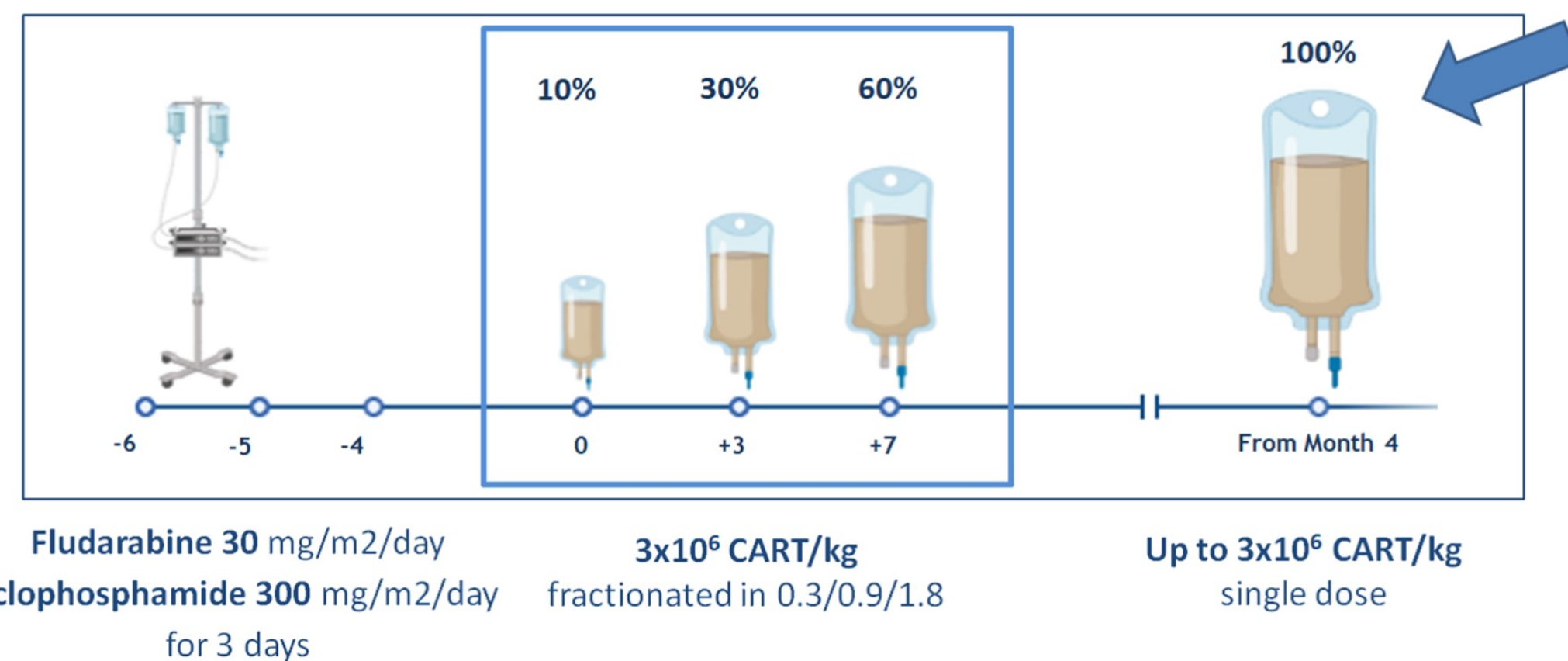
The activity and safety of ARI0002h, an academic autologous CAR T-cell product, has been reported in a pilot multicenter clinical trial (CARTBCMA-HCB-01) treating 30 patients with relapsed/refractory multiple myeloma (RRMM) (NCT04309981) (Oliver-Caldés *et al*, Lancet Onc 2023).

Here, we describe results of the final cohort of 60 patients with longer follow-up.

Methods:

Patients aged 18-75 years old with RRMM were eligible if: measurable disease, refractory to the last line of treatment and received ≥ 2 prior regimens, including a proteasome inhibitor, an immunomodulatory drug and an anti-CD38 antibody.

Primary endpoints were overall response rate (ORR) within the first 3 months and rate of cytokine release syndrome (CRS) and/or neurotoxicity in the first 30 days. Bone marrow minimal residual disease (MRD) was analyzed by next-generation flow at a sensitivity of 10⁻⁶.



Conclusion

Results from 60 patients and a longer follow-up confirm the safety profile and the deep and durable responses obtained after fractionated ARI0002h infusion.



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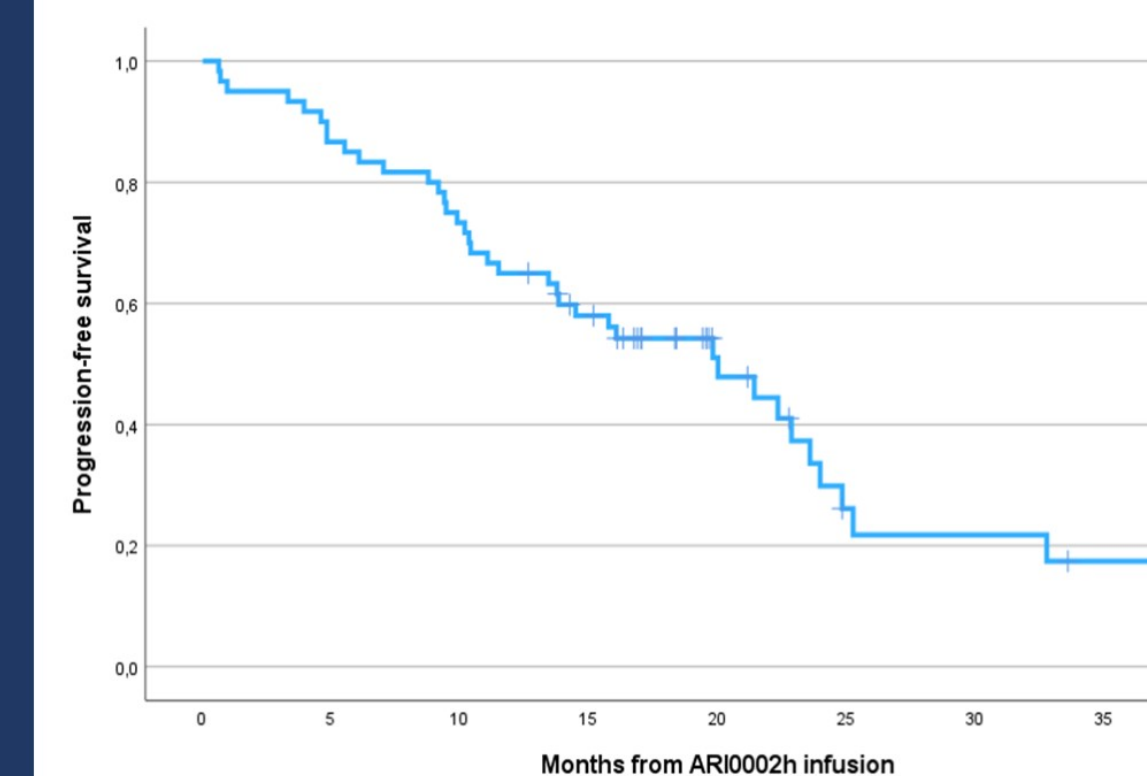
Results:

ORR in the first 3 months was **95%** ($\geq$ very good partial response (VGPR) in 77%). Median time to first response was one month. Responses deepened over time, achieving **58% complete response** (CR) (55% stringent CR).

MRD-negative rates on evaluable samples on days 28 and 100 were **98%** and **96%**, respectively.

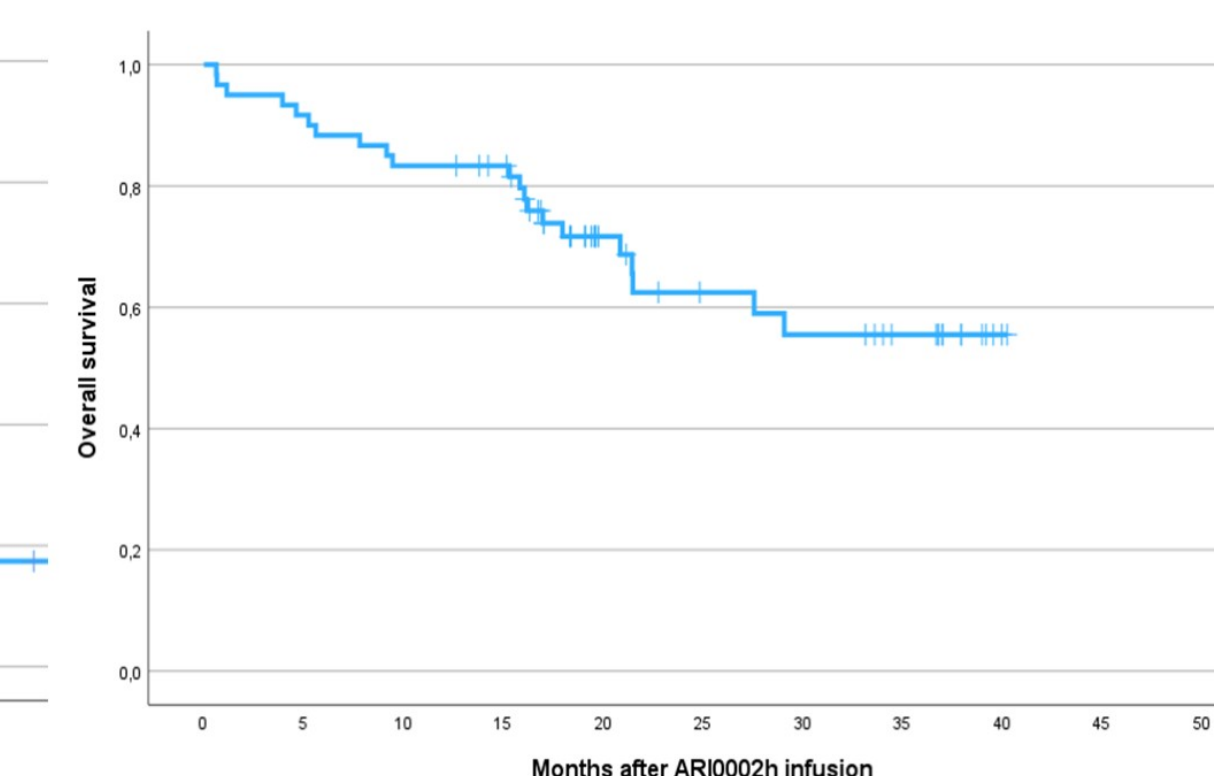
Median follow-up was 24 months (95%CI 9.8-39.9).

Progression-free survival (PFS)



Median PFS 20 months (CI95% 13.2-26.8)

Overall survival (OS)



Median OS was not reached
OS rate at 24 months of 63%

- *CRS was observed in 90% with 5% grades ≥ 3 . Median time to CRS was 7 days (1-14) with a median duration of 4.5 days.
- *Mild ICANS was reported in only 2 patients (3%), with no late neurologic events.
- *6 patients (10%) developed a macrophage activation syndrome (4 grades 1-2, 1 grade 3, 1 grade 5).
- *7 patients (11.7%) developed second primary malignancies after ARI0002h, including 3 skin cancers (one in situ melanoma), 3 solid tumors and one AML.