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ELEVENTH ANNUAL MEETING

ORCA-Q DEMONSTRATES FAVORABLE GVHD-AND-RELAPSE-FREE SURVIVAL IN HAPLOIDENTICAL TRANSPLANTS WITHOUT POST-TRANSPLANT CYCLOPHOSPHAMIDE

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INTRODUCTION

- Allogeneic stem cell transplantation (alloSCT) is curative for several high-risk hematologic malignancies
- Post-transplant cyclophosphamide (PTCy) has enabled a larger number of patients to receive allo SCT using alternative haploidentical (haplo) donors
  - However, GvHD-and-relapse-free survival rates (GRFS) in this population remain low

AIM

- Orca-Q is an investigational, precision-engineered cell therapy biologic; cellular composition includes enriched CD34+ stem cells combined with specific T-cell subsets, and is intended to reconstitute blood and immune systems
- This study explores the role of Orca-Q in patients receiving haploSCT using myeloablative conditioning (MAC) and with single-agent tacrolimus GvHD prophylaxis

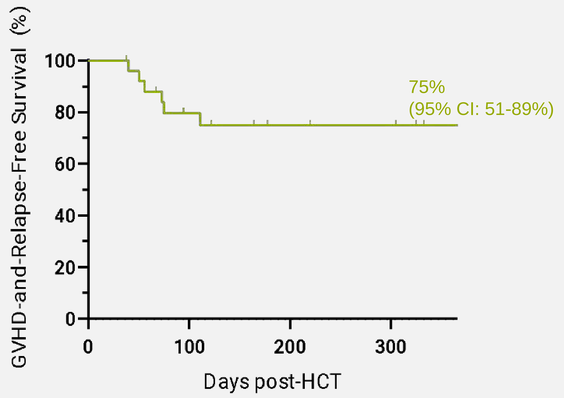
METHODS

- Phase 1, multicenter, dose-expansion study (NCT03802695)
- Haplo SCT with negative DSA
  - Haploidentical (≥ 4/8 but < 7/8 matched related donor at HLA-A, -B, -C, and –DRB1)
- Adult patients (18–65 y) with high-risk hematologic malignancies
  - Acute leukemia (AML, ALL)
  - Myelodysplastic syndrome (very high- or high-risk)
  - Myelofibrosis
  - Eligible for MAC (HCT-CI ≤ 4; KPS ≥ 70; adequate organ function)
- Orca-Q infusion at Day 0
  - Single-agent tacrolimus for GvHD prophylaxis (no PTCy permitted)

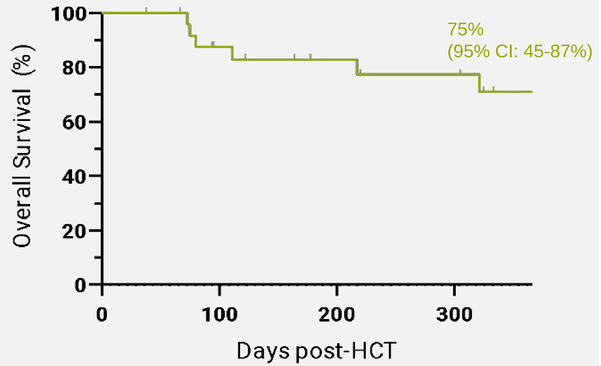
RESULTS

- *26 patients enrolled between January 2019 and July 2022*
  - *Median age 43 years; 18 (69%) male; 10 (39%) Hispanic/ Latino; 15 (58%) AML*
- *No patients had primary graft failure; 2 experienced secondary graft failure*
- *Severe infections were uncommon*
- *Grade ≥ 3 aGvHD was rare (5%) despite using only single-agent tacrolimus as prophylaxis*
- *No moderate-to-severe cGvHD has occurred (median follow-up 211 days)*
  - *Compares favorably to 24%–33% rate post haplo-SCT in historical cohorts[1-3]*
- *Encouraging GRFS and overall survival results*
  - *Compares favorably to 46% rate reported in the context of MAC haploSCT with PTCy[4]*

GvHD-free//Relapse-free Survival



Overall Survival



CONCLUSIONS

- Our findings demonstrate very encouraging outcomes with Orca-Q in the haploSCT setting using myeloablative conditioning and only single-agent tacrolimus
  - Low rates of overall and severe aGvHD and cGvHD
  - Low adverse event profile
  - Improved GRFS
- This phase 1 study continues to enroll patients across the US

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CONTACT INFORMATION

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