

Follow-up Visits:

The patient will have scheduled follow-up visits at the Cancer Center monthly, for five months.

Tests and exams performed during these visits may include:

- Physical Exam
- Routine Labs
- Research Labs
- Imaging by PET/CT, MRI
- Bone Marrow Biopsy

Notes: _____

How do I find out more information?

For patient inquiries and/or questions please contact the clinical trial coordinator:

Alexandra Milhaupt BSN, RN
Immunotherapy Research Nurse
Email: alexandra.milhaupt@charterCARE.org
Office: (401) 456-2526

Trial Sponsor: Sorrento Therapeutics, Inc.
Principle Investigator: Dr. Todd Roberts

Treatment and Follow-up Visit

Locations:

Roger Williams Medical Center
BMT Unit, 1st Floor
825 Chalkstone Avenue
Providence, RI 02908
www.rwmc.org

AND

RWMC Cancer Center Clinic
50 Maude Street, 2nd Floor
Providence, RI 02908
www.weknowcancer.org



ANTI-CD38 CAR-T THERAPY FOR PATIENTS WITH RELAPSED OR REFRACTORY MULTIPLE MYELOMA

Find out if you may qualify for a research trial utilizing Anti-CD38 CAR-T Therapy

SOR-CART-MM-001

Trial Information for Patients & Providers

What is the purpose of this trial?

To assess the effect and safety of a single infusion of CAR2 Anti-CD38 A2 CAR-T cells, in patients with Relapsed or Refractory Multiple Myeloma (**RRMM**), and to determine the recommended phase 2 dose of CAR2 Anti-CD38 A2 CAR-T cells.

Who is Eligible?

- **Population 1:** Adults with RRMM after receiving at least the following:
 - Lenalidomide (Revlimid®)
 - Pomalidomide (Pomalyst®)
 - Bortezomib (Velcade®)
 - Carfilzomib (Kyprolis®)
 - Daratumumab (Darzalex®)
- OR**
- **Population 2:** Adults with RRMM within 1 year of receiving Autologous Stem Cell Transplant
- And**
- Measurable disease
 - No myeloma involvement of the central nervous system, brain metastasis, or spinal cord compression
 - No active plasma cell leukemia
 - Good performance status

How are patients selected?

Patients are pre-screened by the clinical trial team through a combination of patient correspondence, and review of medical records. If a patient appears eligible, they are invited to Roger Williams Medical Center [RWMC] for the official screening period to confirm eligibility.

Research Title: *A Phase 1, Open-Label, Dose-Escalation, Pharmacokinetic, and Pharmacodynamic Study of the Safety and Efficacy of CAR2 Anti-CD38 A2 CAR-T Cells in Patients with Relapsed or Refractory Multiple Myeloma*

What can trial participants expect?

- **Leukapheresis:** If the patient is eligible, he/she will undergo Leukapheresis. During this procedure, the patient's T-cells are collected then re-programmed into Anti-CD38 CAR-T cells.



Treatment (28-day cycle) Includes:

- A single infusion of Cyclophosphamide is given 2 days before receiving CAR-T cells
- A single infusion of Anti-CD38 CAR-T cells is given through intravenous (IV) access
- Patient is admitted to the hospital for at least 7 days following infusion of CAR-T cells
- Outpatient clinic visits after hospital discharge
- Patients will have access to this investigational treatment
 - Not yet FDA approved
 - Safety and effectiveness is not yet known

Location of Treatment:

- Treatment is performed at RWMC in the Blood and Marrow Transplant (BMT) unit
- Patient must remain within 40 miles of RWMC during treatment period
- Follow-up visits occur at the RWMC Cancer Center