**Patient Population**

See Section 3.0 for Complete Eligibility Details

**Eligibility for Screening (Step 0 – Pre-registration):**
- Age ≥ 18 and ≤ 70 years
- Must have histologically confirmed mantle cell lymphoma, with cyclin D1 by immunohistochemical stains and/or t (11;14) by cytogenetics/FISH
- Enrolling physician must feel that the patient is a candidate for autologous stem cell transplantation
- May be about to begin/be receiving/have completed induction therapy within 120 days prior to pre-registration to Step 0. No more than 300 days may have passed between the first day of induction therapy and pre-registration
  - For patients that completed induction therapy, restaging evaluation must show PR/CR; post-induction patients with clinical disease progression are not eligible for pre-registration
  - Up to 2 regimens of chemotherapy are allowed as long as continuous response was ongoing throughout therapy (a PR must be achieved)
- No documented history of CNS involvement by mantle cell lymphoma

**Eligibility for Treatment Assignment (Step 1):**
- Proliferation rate, using Ki-67/MIB-1 must be documented
- Must have received results from FFPE submission: MRD Indeterminate, or identified unique clonal immunoglobulin DNA sequence and MRD assessment completed
- Must have completed induction therapy within 150 days prior to registration to Step 1 AND no more than 300 days elapsed from the first dose of induction chemo given, until the last day of induction chemo administered
  - Must have received at least 4 cycles; up to 2 regimens allowed as long as continuous response was ongoing
- ECOG PS 0-2; must have radiologic complete/partial remission (Lugano)
- HIV positive patients must meet criteria per protocol

**Treatment Plan**

See Section 5.0 for Complete Treatment Details

**Patient treatment assignment is as follows:**
- Clonal molecular marker identified + blood MRD negative + complete response: Arms A or B
- Clonal molecular marker identified + blood MRD positive + complete/partial response: Arm C
- Clonal molecular marker identified + blood MRD indeterminate + complete/partial response: Arm D
- No clonal molecular marker identified OR clonal molecular marker + blood MRD negative + partial response: Arm D

**Arm A:** HCT; Rituximab maintenance 375 mg/m² IV or Rituxan Hycela 1400 mg/23,400 units SQ every 8 weeks (+/- 1 wk) x 18 doses (to begin 100-140 days after transplant)

**Arm B:** Rituximab maintenance 375 mg/m² IV or Rituxan Hycela 1400 mg/23,400 units SQ every 8 weeks (+/- 1 wk) x 18 doses (to begin 40-140 days after completion of induction therapy)

**Arm C:** HCT (Note: blood must be submitted at Day 100 [+/- 5 days] post-transplant for MRD assessment); Rituximab maintenance 375 mg/m² IV or Rituxan Hycela 1400 mg/23,400 units SQ every 8 weeks (+/- 1 wk) x 18 doses (to begin 100-140 days after transplant)

**Arm D:** HCT; Rituximab maintenance 375 mg/m² IV or Rituxan Hycela 1400 mg/23,400 units SQ every 8 weeks (+/- 1 wk) x 18 doses (to begin 100-140 days after transplant)

**Notes:**
- Remission induction therapy is not considered an aspect of protocol therapy, but the therapy may impact the patient’s eligibility to register to treatment (see protocol for details)
- HCT will be performed per institutional guidelines (see protocol for details)
- Rituximab administration to be managed per standard of care

**Patient Enrollment**

All Sites: Oncology Patient Enrollment Network (OPEN) [https://open.ctsu.org](https://open.ctsu.org)

**Protocol Information**

ECOG-ACRIN Operations-Boston: 857-504-2900, [http://ecog-acrin.org](http://ecog-acrin.org) (Member Login)

Please Enroll Your Eligible Patients!