

## **DLBCL/Aggressive NHL**

### **A Phase 1b Dose Escalation Study Of Metabolically Fit Cd19 Chimeric Antigen Receptor (Car) T Cells With Cd34 Selection Markers In Adult Patients With Relapsed Or Refractory Cd19 B Cell NHL and CLL/SLL**

- Patient population/Notes: This trial offers CD19 CAR T cell therapy manufactured here at MUSC/HCC to patients with relapsed B-cell NHL (DLBCL, FL, MCL, MZL, LPL, CLL/SLL). Currently in phase 1 dose escalation and enrolling quickly..

### **A Randomized Phase II Trial of Consolidation Therapy Following CD19 CAR T Cell Treatment for Relapsed/Refractory Large B Cell Lymphoma or Grade IIIB Follicular Lymphoma**

- Patient population/Notes: Patients will be registered prior to CAR-T cell therapy and if they have SD/PR at one month PET-CT they will be eligible to be randomized to Mosunetuzumab, Polatuzumab, Mosun+Pola, or observation (30 patients in each of the 4 arms) as the majority of these patients currently relapse. If patients have CR at one month PET-CT they will be followed for MRD analysis as will the patients with SD/PR. Very excited to have this trial open here and at multiple centers throughout the country.

### **A Phase Ib Trial of Zanubrutinib in Combination with R-CHP + Pola (ZaRCHP+Pola) for Patients with Newly Diagnosed Diffuse Large B Cell Lymphoma**

- Patient population/notes: Open to all patients with IPI  $\geq 2$  with newly diagnosed DLBCL. This trial is currently on hold with as the backbone will be changing from R-CHOP to R-CHP + Pola but hopefully it will open later this month or early next month. Patients can receive one cycle of SOC chemotherapy prior to enrolling as an FYI.

### **A Phase 1b Open-Label Study to Evaluate the Safety and Anti-cancer Activity of Loncastuximab Tesirine in Combination with Novel Therapies in Patients with Relapsed or Refractory B-cell Non-Hodgkin Lymphoma**

- Patient population/notes: Loncastuximab is a CD19 antibody drug conjugate (like BV but targets CD19) that received FDA approval in 2021 for R/R DLBCL. This Trial is investigating the combination of ADCT-402 with BiTE therapy (both mosunetuzumab and glofitamab) and will enroll R/R patients with DLBCL, FL, MCL, MZL, and BL and is open for enrollment.

### **A Phase II/III Randomized Study of R-Mini-CHOP With or Without CC-486 (Oral Azacitidine) in Patients Age 75 Years or Older With Newly Diagnosed Diffuse Large B Cell Lymphoma, Grade IIIB Follicular Lymphoma, Transformed Lymphoma, and High-Grade B-Cell Lymphomas With MYC and BCL2 and/or BCL6 Rearrangements**

- Patient population/Notes: Cooperative group trial for newly diagnosed elderly DLBCL patients. These patients typically do not well and are not candidates for clinical trials, so we are very happy to offer this trial here at Hollings!

## **Classical Hodgkin Lymphoma**

**A Randomized, Phase 3 Interim Response Adapted Trial Comparing Standard Therapy with Immuno-oncology Therapy for Children and Adults with Newly Diagnosed Stage I and II Classic Hodgkin Lymphoma**

- Patient population/Notes: cooperative group trial in which all patients with limited stage disease receive 2 cycles of ABVD and are randomized to novel therapy (BV+Nivo) vs standard of care therapy based on interim PET-CT.

**Mantle Cell Lymphoma**

**A Phase 1b Dose Escalation Study Of Metabolically Fit CD19 Chimeric Antigen Receptor (Car) T Cells With Cd34 Selection Markers In Adult Patients With Relapsed Or Refractory CD19 B Cell NHL and CLL/SLL**

- Patient population/Notes: This trial offers CD19 CAR T cell therapy manufactured here at MUSC/HCC to patients with relapsed B-cell NHL (DLBCL, FL, MCL, MZL, LPL, CLL/SLL). Currently in phase 1 dose escalation and enrolling quickly..

**A Randomized Phase III Trial of Consolidation with Autologous Hematopoietic Cell Transplantation Followed by Maintenance Rituximab vs Maintenance Rituximab Alone for Patients with Mantle Cell Lymphoma in Minimal Residual Disease Negative First Complete Remission.**

- Patient Population/Notes: Cooperative group study where patients will be randomized to auto SCT + maintenance rituximab vs maintenance rituximab alone. If you have any patients currently receiving induction for MCL please consider sending them here during induction for the initial visit and we can plan on screening them once induction is completed.

**A Phase 1b Open-Label Study to Evaluate the Safety and Anti-cancer Activity of Loncastuximab Tesirine in Combination with Novel Therapies in Patients with Relapsed or Refractory B-cell Non-Hodgkin Lymphoma**

- Patient population/notes: Loncastuximab is a CD19 antibody drug conjugate (like BV but targets CD19) that received FDA approval in 2021 for R/R DLBCL. This Trial is investigating the combination of ADCT-402 with BiTE therapy (both mosunetuzumab and glofitamab) and will enroll R/R patients with DLBCL, FL, MCL, MZL, and BL and is open for enrollment.

**Indolent NHL**

**A Phase 1b Dose Escalation Study Of Metabolically Fit CD19 Chimeric Antigen Receptor (Car) T Cells With Cd34 Selection Markers In Adult Patients With Relapsed Or Refractory CD19 B Cell NHL and CLL/SLL**

- Patient population/Notes: This trial offers CD19 CAR T cell therapy manufactured here at MUSC/HCC to patients with relapsed B-cell NHL (DLBCL, FL, MCL, MZL, LPL, CLL/SLL). Currently in phase 1 dose escalation and enrolling quickly..

**A Phase 1b Open-Label Study to Evaluate the Safety and Anti-cancer Activity of Loncastuximab Tesirine in Combination with Novel Therapies in Patients with Relapsed or Refractory B-cell Non-Hodgkin Lymphoma**

- Patient population/notes: Loncastuximab is a CD19 antibody drug conjugate (like BV but targets CD19) that received FDA approval in 2021 for R/R DLBCL. This Trial is investigating the combination of ADCT-402 with BiTE therapy (both mosunetuzumab and glofitamab) and will enroll R/R patients with DLBCL, FL, MCL, MZL, and BL and is open for enrollment.

### **CLL/SLL**

#### **Randomized, Phase III Study of Early Intervention with Venetoclax and Obinutuzumab Versus Delayed Therapy with Venetoclax and Obinutuzumab in Newly Diagnosed Asymptomatic High-Risk Patients with Chronic Lymphocytic Leukemia / Small Lymphocytic Lymphoma (CLL/SLL): EVOLVE CLL/SLL Study.**

- Patient population/notes: This trial randomizes patients dx with CLL/SLL that do not currently have a treatment indication but have 'high risk' disease. High risk disease is defined as having a CLL-IPI score of  $\geq 4$  OR having complex cytogenetics (3+ chromosomal abnormalities). Patients can be enrolled up to 12 months from their initial diagnosis and would be assigned to Ven+obinutuzumab at randomization or to 'delayed therapy' once they develop a traditional treatment indication. Whether patients are treated 'early' or 'delayed' they would have treatment paid for by study - Please call if any questions about patients or trial!

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- Patient population/Notes: This trial offers CD19 CAR T cell therapy manufactured here at MUSC/HCC to patients with relapsed B-cell NHL (DLBCL, FL, MCL, MZL, LPL, CLL/SLL). Currently in phase 1 dose escalation and enrolling quickly..

### **T-cell NHL**

#### **A Randomized Phase II Study of CHO(E)P vs CC-486-CHO(E)P vs Duvelisib-CHO(E)P in Previously Untreated CD30 Negative Peripheral T-Cell Lymphomas**

- Patient population/notes: Cooperative group study for frontline PTCL patients that are CD30 negative (standard for CD30+ patients frontline is CHP+BV). Duvelisib is a PI3K inhibitor and CC-486 is an oral hypomethylating agent. Patients would be eligible for auto SCT after trial. Please call Brian Greenwell if you think you have a patient!

#### **A Multi-Center Phase Ib Trial Evaluating the Safety and Efficacy of Lacutamab in Patients With Relapse Peripheral T-Cell Lymphoma That Express KIR3DL2**

- Patient population/notes: Lacutamab is a monoclonal antibody against KIR3DL2, which is expressed in ~50% of PTCL. Promising activity has already been seen in CTCL (MF/SS) and has been well tolerated. Enrolls patients with between 1 and 3 lines of therapy, but of note, they cannot have primary refractory disease. Brian G recommends referral of any T-cell lymphoma patients (even if currently in remission) who may be candidates in the future, as the company allows us to "prescreen" patients for KIR3DL2 expression from their initial diagnostic sample.

**An Open-Label, Phase 2 Trial of Nanatinostat in Combination with Valganciclovir in Subjects With Epstein-Barr Virus-Positive (EBV+) Relapsed/Refractory Lymphomas (NAVAL-1)**

- Patient population/Notes: This trial will be open for multiple subtypes of EBV+ R/R NHL including PTCL, AITL, PTLN, or other EBV+ NHL. Great trial for many patients without clinical trial options otherwise.