**Protocol Title:** A Phase III, Multicenter, Randomized, Double-Blind, Placebo-Controlled Trial Comparing the Efficacy and Safety of Polatuzumab Vedotin in Combination with Rituximab and CHP (R-CHP) Versus Rituximab and CHOP (R-CHOP) in Previously Untreated Patients with Diffuse Large B-Cell Lymphoma

**Target Population:** Diffuse Large B-Cell Lymphoma (DLBCL)

**Summary:** This Phase III, randomized, double-blind, placebo-controlled study will compare the efficacy, safety, and pharmacokinetics of Polatuzumab Vedotin plus R-CHP versus R-CHOP in participants with previously untreated Diffuse Large B-Cell Lymphoma (DLBCL).

**Key Inclusion Criteria:**
- Previously untreated CD20-Positive DLBCL, including one of the following lymphoid neoplasms:
  - DLBCL, not otherwise specified (NOS) including Germinal Center B-Cell type, activated B-Cell type
  - T-cell/Histiocyte-Rich Large B-Cell Lymphoma
  - Epstein-Barr Virus-Positive DLBCL, NOS
  - Anaplastic Lymphoma Kinase (ALK)-Positive Large B-Cell Lymphoma
  - Human Herpesvirus-8 (HHV8)-Positive DLBCL, NOS
  - High-grade B-Cell Lymphoma with MYC and BCL2 and/or BCL6 rearrangements (double-hit or triple-hit Lymphoma)
  - High-grade B-Cell Lymphoma, NOS
- Availability of archival or freshly collected tumor tissue before study enrollment.
- International Prognostic Index (IPI) score of 2-5.
- ECOG Performance Status of 0, 1, or 2.
- Life expectancy greater than or equal to ≥ 12 Months.
- LVEF ≥ 50% on cardiac MUGA scan or cardiac ECHO.
- Adequate hematologic function.

**Key Exclusion Criteria:**
- History of severe allergic or anaphylactic reactions to humanized or murine monoclonal antibodies or known sensitivity or allergy to murine products.
- Contraindication to any of the individual components of CHOP, including prior receipt of Anthracyclines.
- Prior organ transplantation.
- History of demyelinating form of Charcot-Marie-Tooth disease, Indolent Lymphoma, Follicular Lymphoma grade 3B, B-Cell Lymphoma, unclassifiable, with features intermediate between DLBCL and Classical Hodgkin Lymphoma (grey-zone lymphoma), Primary Mediastinal (Thymic) Large B-Cell Lymphoma, or Burkitt Lymphoma.
- Prior treatment with cytotoxic drugs within 5 Years of screening for any condition (example [e.g.,] cancer, rheumatoid arthritis) or prior use of any anti-CD20 antibody.
- Prior use of any monoclonal antibody within 3 Months of the start of Cycle 1.
- Prior therapy for DLBCL, with the exception of nodal biopsy.
- CNS lymphoma (primary or secondary involvement), primary effusion DLBCL, or primary cutaneous DLBCL.
- Prior radiotherapy to the mediastinal/pericardial region.
- Positive results for the Human T-Lymphotrophic 1 Virus (HTLV-1).
- History of Progressive Multifocal Leukoencephalopathy.

**Contacts:**
- **Principal Investigator:** Carter Davis, MD
- **Research Nurses (RN):** Elise Curry (elisemarie.curry@ochners.org, ext. 28084)
  Stephanie Green (stephanie.green2@ochners.org, ext. 23918)

**For additional information:** [https://clinicaltrials.gov/ct2/show/NCT03274492](https://clinicaltrials.gov/ct2/show/NCT03274492)

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