CHOA Clinical Trial Master List

FOLLICULAR LYMPHOMA

INCB 50465-203: A Phase 2, Multicenter, Open-Label, Randomized Study Comparing INCB050465, a PI3K δ Inhibitor, to Idelalisib in Relapsed or Refractory Follicular Lymphoma (CITADEL-203)	
Sponsor: Incyte	Therapy Line: **Relapsed or Refractory** Drug Classification: **PI3K δ Inhibitor**
Principal Investigator: David Ellison, MD	**CRC:** Ashley Morrill ext. 291
Basic Enrollment Information Criteria: Histologically confirmed, relapsed or refractory, follicular B-cell non-Hodgkin lymphoma (NHL) (FL) Grade 1, 2, and 3a. Ineligible for hematopoietic stem cell transplant. **Must have been treated with at least 2 prior systemic therapies.** Radiographically measurable lymphadenopathy or extra nodal lymphoid malignancy (defined as the presence of ≥ 1 lesion that measures > 1.5 cm in the longest dimension and ≥ 1.0 cm in the longest perpendicular dimension as assessed by computed tomography (CT) or magnetic resonance imaging (MRI). Subjects must be willing to undergo an incisional, excisional, or core needle lymph node or tissue biopsy or provide a lymph node or tissue biopsy from the most recent available archival tissue. ECOG performance status 0 to 2. **Exclusion Criteria:** Known histological transformation from indolent NHL to diffuse large B-cell lymphoma. History of central nervous system lymphoma (either primary or metastatic). **Prior treatment with idelalisib (Zydelig), other selective phosphatidylinositol 3-kinase (PI3K) δ inhibitors, or a pan-PI3K inhibitor.** Prior treatment with a Bruton's tyrosine kinase inhibitor (eg, ibrutinib - Imbruvica). Allogeneic stem cell transplant within the last 6 months, or autologous stem cell transplant within the last 3 months before the date of randomization. Active graft-versus-host disease. Evidence of hepatitis B virus (HBV) or hepatitis C virus (HCV) infection or risk of reactivation: HBV DNA and HCV RNA must be undetectable. Subjects cannot be positive for hepatitis B surface antigen or anti–hepatitis B core antibody. Subjects who have positive anti-HBs as the only evidence of prior exposure may participate in the study provided that there is both 1) no known history of HBV infection and 2) verified receipt of hepatitis B vaccine.	

LYMPHOMA – Marginal Zone Lymphoma

INCB 50465-204: A Phase 2, Open-Label, 2-Cohort Study of INCB050465, a PI3K δ Inhibitor, in Subjects With Relapsed or Refractory Marginal Zone Lymphoma With or Without Prior Exposure to a BTK Inhibitor (CITADEL-204)	
Sponsor: Incyte	Therapy Line: **Relapsed or Refractory** Drug Classification: **PI3K δ Inhibitor**
Principal Investigator: David Ellison, MD	**CRC:** Stephanie Patel ext.212
Basic Enrollment Information Criteria: Men and women, aged 18 or older (except in South Korea, aged 19 or older). Radiographically measurable lymphadenopathy or extranodal lymphoid malignancy (defined as the presence of ≥ 1 lesion that measures > 1.5 cm in the longest transverse diameter (LDi) and ≥ 1.0 cm in the longest perpendicular diameter as assessed by CT or magnetic resonance imaging (MRI). Subjects with splenic MZL who do not meet the radiographically measurable disease criteria described herein are eligible for participation provided that bone marrow infiltration of MZL is histologically confirmed. Subjects must be willing to undergo an incisional or excisional lymph node or tissue biopsy or provide a lymph node or tissue biopsy from the most recent available archival tissue. Eastern Cooperative Oncology Group (ECOG) performance status 0 to 2. **Exclusion Criteria:** Evidence of diffuse large B-cell transformation. History of central nervous system lymphoma (either primary or metastatic) or leptomeningeal disease. Prior treatment with idelalisib (Zydelig), other selective PI3K δ inhibitors, or a pan-PI3K inhibitor. Allogeneic stem cell transplant within the last 6 months, or autologous stem cell transplant within the last 3 months before the date of the first dose of study treatment. Active graft versus host disease. Liver disease: Evidence of hepatitis B virus (HBV) or hepatitis C virus (HCV) infection or risk of reactivation.	