

KARTA BADANIA
NAZWA BADANIA: A PHASE 1 STUDY TO ASSESS SAFETY AND TOLERABILITY OF REGN1979, AN ANTI-CD20 X ANTI-CD3 BISPECIFIC MONOCLONAL ANTIBODY, AND REGN2810, AN ANTI-PROGRAMMED DEATH-1 MONOCLONAL ANTIBODY, IN PATIENTS WITH B-CELL MALIGNANCIES
NUMER PROTOKOŁU: R1979-ONC-1504
WSKAZANIE- C85 - Inne i nieokreślone postacie chłoniaka nieziarniczego

Key Inclusion Criteria:

1. Have documented CD20+ aggressive B-cell NHL that is either not responsive to or relapsed after at least 2 prior lines of systemic therapy, for whom treatment with an anti-CD20 antibody may be appropriate. In addition, prior treatments should at least contain an anti-CD20 antibody and an alkylating agent.
2. Must have at least 1 nodal lesion (≥ 1.5 cm), or at least one extranodal lesion with longest transverse diameter (LDi) greater than 1.0 cm, documented by diagnostic imaging (computed tomography [CT] or magnetic resonance imaging [MRI]).
3. Eastern Cooperative Oncology Group (ECOG) performance status ≤ 1
4. Adequate bone marrow and hepatic function, as defined in the protocol
5. Willing and able to comply with clinic visits and study-related procedures
6. Provide signed informed consent

Key Exclusion Criteria:

1. Primary central nervous system (CNS) lymphoma, or known or suspected CNS involvement by non-primary CNS NHL
 2. History of or current relevant CNS pathology, as described in the protocol
 3. Ongoing or recent (within 2 years) evidence of significant autoimmune disease that required treatment with systemic immunosuppressive treatments, which may suggest risk for immune-mediated adverse events (iAEs)
 4. Prior therapies, as described in the protocol
 5. Uncontrolled infection with human immunodeficiency virus (HIV), hepatitis B or hepatitis C infection or other uncontrolled infection
 6. Cytomegalovirus infection as noted by detectable levels on peripheral blood polymerase chain reaction (PCR) assay until the infection is well controlled.
 7. Known hypersensitivity to both allopurinol and rasburicase
 8. Pregnant or breastfeeding women
 9. Women of childbearing potential, or men who are unwilling to practice highly effective contraception prior to the initial dose/start of the first treatment, during the study, and for at least 6 months after the last dose, as defined in the protocol
 10. Patients prior diagnosis of hemophagocytic lymphohistiocytosis (HLH) or macrophage activation syndrome (MAS)
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