

KARTA BADANIA
NAZWA BADANIA: A Phase 3, Open-label, Randomized Study to Compare the Efficacy and Safety of Odronextamab (REGN1979), an Anti-CD20 X Anti-CD3 Bispecific Antibody Versus Investigator's Choice in Previously Untreated Participants With Follicular Lymphoma (OLYMPIA-1)
NUMER PROTOKOŁU: R1979-HM-2298
WSKAZANIE- Chłoniak nieziarniczny guzkowy, nieokreślony

KRYTERIA WŁĄCZENIA I WYŁĄCZENIA

Key Inclusion Criteria:

1. Diagnosis of cluster of differentiation 20⁺ (CD20⁺) FL Grade 1-3a, stage II bulky or stage III / IV
2. Need for treatment as described in the protocol
3. Have measurable disease on cross-sectional imaging documented by diagnostic imaging Computed tomography (CT) or Magnetic resonance imaging (MRI)
4. Eastern Cooperative Oncology Group (ECOG) performance status of 0-2
5. Adequate bone marrow function and hepatic function

Key Exclusion Criteria:

1. Central nervous system (CNS) lymphoma or leptomeningeal lymphoma
 2. Histological evidence of transformation to a high-grade or diffuse large B-cell lymphoma
 3. Waldenström macroglobulinemia (WM, lymphoplasmacytic lymphoma), Grade 3b follicular lymphoma, chronic lymphocytic leukemia, or small lymphocytic lymphoma
 4. Treatment with any systemic anti-lymphoma therapy
 5. Infections and allergy/hypersensitivity to study drug or excipient
-