KARTA BADANIA
NAZWA BADANIA: A Phase 3, Open-Label, Randomized Study to Compare the Efficacy and Safety of Odronextamab (REGN1979), an Anti-CD20x Anti-CD3 Bispecific Antibody, Combined With Chemotherapy Versus Rituximab Combined With Chemotherapy in Previously Untreated Participants With Follicular Lymphoma (OLYMPIA-2)
NUMER PROTOKOŁU: R1979-ONC-2075
WSKAZANIE- Chłoniak nieziarniczy guzkowy, nieokreślony

KRYTERIA WŁĄCZENIA I WYŁĄCZENIA

Key Inclusion Criteria:

1. Have diagnosis of cluster of differentiation 20 positive (CD20+) FL grade 1-3a, stage II bulky or stage III / IV
    1. For Part 1A: previously untreated participants who have Follicular Lymphoma International Prognostic Index (FLIPI)-1 score of 3 to 5, or R/R FL who have not received R-CHOP or R-CVP.
    2. For Part 1B: previously untreated participants who have FLIPI-1 score of 3 to 5
    3. For Part 2: previously untreated participants who have FLIPI-1 score of 0 to 5
2. Have measurable disease on cross sectional imaging documented by diagnostic computed tomography [CT], or magnetic resonance imaging [MRI] imaging, as described in the protocol
3. Eastern Cooperative Oncology Group (ECOG) performance status of 0-2
4. Adequate bone marrow and hepatic function.
5. Key Exclusion Criteria:

1. Participants with central nervous system lymphoma or leptomeningeal lymphoma
2. Participants with histological evidence of transformation to a high-grade or diffuse large B-cell lymphoma
3. Participants with Waldenström macroglobulinemia (WM, lymphoplasmacytic lymphoma), grade 3b follicular lymphoma, chronic lymphocytic leukemia or small lymphocytic lymphoma
4. Recent major surgery and history or organ transplantation
5. A malignancy other than NHL unless the participant is adequately and definitively treated and any other significant active disease or medical condition that could interfere with the conduct of the study or put the participant at significant risk, as described in the protocol.