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, in Combination With Lenalidomide Versus Rituximab in Combination With Lenalidomide Therapy in Relapsed/Refractory Participants With Follicular Lymphoma and Marginal Zone Lymphoma (OLYMPIA-5)
NUMER PROTOKOŁU: **R1979-ONC-22102**
WSKAZANIE- Chłoniak nieziarniczy guzkowy [grudkowy]

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Key Inclusion Criteria:

1. Local histologic confirmation of FL grade 1-3a or MZL (nodal, splenic, or extra nodal MZL) as assessed by the investigator.
2. Must have refractory disease or relapsed after at least 2 cycles of prior systemic chemo-immunotherapy or immunotherapy. Prior systemic therapy should have included at least one anti-cluster of differentiation 20 (CD20) monoclonal antibody and patient should meet indication for treatment.
3. Have measurable disease on cross sectional imaging documented by diagnostic computed tomography [CT], or magnetic resonance imaging [MRI] imaging, as described in the protocol.
4. Eastern Cooperative Oncology Group (ECOG) performance status of 0 to 2.
5. Adequate hematologic and organ function.

Key Exclusion Criteria:

1. Primary central nervous system (CNS) lymphoma or known involvement (either current or prior history of CNS involvement) by non-primary CNS NHL.
2. Participants with histological evidence of transformation to a high-grade or diffuse large B-cell lymphoma, or any histology other than FL grade 1-3a or MZL.
3. History of or current relevant CNS pathology, as described in the protocol.
4. A malignancy other than NHL unless the participant is adequately and definitively treated and is cancer free for at least 3 years, with the exception of localized prostate cancer treated with hormone therapy or local radiotherapy (ie, pellets), cervical carcinoma in situ, breast cancer in situ, or nonmelanoma skin cancer that was definitively treated.
5. 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.
6. Allergy/hypersensitivity to study drugs or excipients.

7. Active infection as defined in the protocol.