

<b>KARTA BADANIA</b>
<b>NAZWA BADANIA: A Study of Zilovetamab Vedotin (MK-2140) in Combination With Standard of Care in Participants With Relapsed or Refractory Diffuse Large B-Cell Lymphoma (rrDLBCL) (MK-2140-003)</b>
<b>NUMER PROTOKOŁU: MK-2140-003</b>
<b>WSKAZANIE- With Relapsed or Refractory Diffuse Large B-Cell Lymphoma</b>

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**Inclusion Criteria:**

- Has a histologically confirmed diagnosis of Diffuse Large B-Cell Lymphoma (DLBCL).
- Has radiographically measurable DLBCL per the Lugano Response Criteria, as assessed locally by the investigator.
- Has an Eastern Cooperative Oncology Group (ECOG) Performance Status of 0 to 2 within 7 days prior to study treatment initiation.
- Has adequate organ function.
- Is able to provide new or archival tumor tissue sample not previously irradiated.

**Zilovetamab vedotin plus R-GemOx, or R-GemOx study arms:**

- Has relapsed or refractory DLBCL and is ineligible for or have failed autologous stem-cell transplant (ASCT) and have failed at least 1 line of prior therapy.
- Has post-chimeric antigen receptor T (post-CAR-T) cell therapy failure or is ineligible for CAR-T cell therapy.

**Not applicable with protocol amendment 4: Zilovetamab vedotin plus Bendamustine Rituximab (BR), and Bendamustine Rituximab study arms:**

- Has relapsed or refractory DLBCL and is ineligible for or have failed ASCT and have failed at least 2 lines of prior therapy.
- Has post-CAR-T therapy failure or is ineligible for CAR-T cell therapy.

**Exclusion Criteria:**

- Not applicable with protocol amendment 4: Has history of transformation of indolent disease to DLBCL
  - Has received solid organ transplant at any time.
  - Has received a diagnosis of primary mediastinal B-cell lymphoma (PMBCL).
  - Has clinically significant (ie, active) cardiovascular disease or serious cardiac arrhythmia requiring medication.
  - Has ongoing graft-versus-host disease (GVHD) of any grade, or is receiving treatment for their GVHD.
  - Has pericardial effusion or clinically significant pleural effusion.
  - Has ongoing Grade >1 peripheral neuropathy.
  - Has a history of a second malignancy, unless potentially curative treatment has been completed with no evidence of malignancy for 2 years.
  - Has a demyelinating form of Charcot-Marie-Tooth disease.
  - Has contraindication to any of the study intervention components including but not limited to prior anaphylactic reaction.
  - Has received prior systemic anticancer therapy, including investigational agents within 4 weeks prior to the first dose of study intervention.
  - Has received prior radiotherapy within 4 weeks of start of study intervention. Participants must have recovered from all radiation-related toxicities, not require corticosteroids, and not have had radiation pneumonitis.
  - Has ongoing corticosteroid therapy.
  - Has received a live or live-attenuated vaccine within 30 days before the first dose of study intervention.
  - Is currently participating in or has participated in a study of an investigational agent or has used an investigational device within 4 weeks before the first dose of study intervention.
  - Has known active central nervous system (CNS) lymphoma involvement or active CNS involvement by lymphoma. Participants with prior CNS involvement are eligible if their CNS disease is in radiographic, cytological (for cerebrospinal fluid disease), and clinical remission.
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- Has an active infection requiring systemic therapy.
  - Has a known history of human immunodeficiency virus (HIV) infection.
  - Has a known active Hepatitis C virus infection.
  - Has a known psychiatric or substance abuse disorder that would interfere with the participant's ability to cooperate with the requirements of the study.
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