

KARTA BADANIA
NAZWA BADANIA: A Clinical Study of Zilovetamab Vedotin (MK-2140) Plus Rituximab Plus Cyclophosphamide, Doxorubicin, and Prednisone (R-CHP) Versus Polatuzumab Vedotin Plus R-CHP in People With Diffuse Large B-cell Lymphoma (DLBCL) (MK-2140-011/waveLINE-011)
NUMER PROTOKOŁU: MK-2140-011
WSKAZANIE- C83.3 - Z dużych komórek (rozlany)

Inclusion criteria

The main inclusion criteria include but are not limited to the following:

- Has histologically confirmed diagnosis of germinal center B-cell (GCB) subtype of diffuse large B-cell lymphoma (DLBCL), by prior biopsy, according to the World Health Organization (WHO) classification of neoplasms of the hematopoietic and lymphoid tissues.
- Has positron emission tomography (PET) positive disease at screening, defined as 4 to 5 on the Lugano 5-point scale.
- Has received no prior treatment for their DLBCL.
- Human immunodeficiency virus (HIV) infected participants must have well controlled HIV on antiretroviral therapy (ART).
- Participants who are hepatitis B surface antigen (HBsAg) positive are eligible if they have received hepatitis B virus (HBV) antiviral therapy and have undetectable HBV viral load prior to randomization.
- Participants with history of hepatitis C virus (HCV) infection are eligible if HCV viral load is undetectable at screening.

Exclusion criteria

The main exclusion criteria include but are not limited to the following:

- Has a history of transformation of indolent disease to DLBCL.
 - Has received a diagnosis of primary mediastinal B-cell lymphoma (PMBCL) or Grey zone lymphoma.
 - Has Ann Arbor Stage I DLBCL.
 - Has clinically significant (i.e., active) cardiovascular disease: cerebral vascular accident/stroke (<6 months prior to enrollment), myocardial infarction (<6 months prior to enrollment), unstable angina, congestive heart failure (New York Heart Association Classification Class \geq II), or serious cardiac arrhythmia requiring medication.
 - Has clinically significant pericardial or pleural effusion.
 - Has ongoing Grade >1 peripheral neuropathy.
 - Has a demyelinating form of Charcot-Marie-Tooth disease.
 - HIV-infected participants with a history of Kaposi's sarcoma and/or Multicentric Castleman's Disease.
 - Has ongoing corticosteroid therapy.
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- Known additional malignancy that is progressing or has required active treatment within the past 2 years.
 - Known active central nervous system (CNS) lymphoma.
 - Has active autoimmune disease that has required systemic treatment in the past 2 years.
 - Has active infection requiring systemic therapy.
 - Has active HBV (defined as HBsAg positive and detectable HBV deoxyribonucleic acid (DNA)) and HCV (defined as anti-HCV antibody positive and detectable HCV ribonucleic acid (RNA)) infection.
 - Has history of stem cell/solid organ transplant.
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