KARTA BADANIA
NAZWA BADANIA: A Phase 3, Randomized Study to Compare Nemtabrutinib Versus Comparator (Investigator's Choice of Ibrutinib or Acalabrutinib) in Participants With Untreated Chronic Lymphocytic Leukemia/Small Lymphocytic Lymphoma (BELLWAVE-011)
NUMER PROTOKOŁU: **MK-1026-011**
WSKAZANIE- Przewlekła białaczka limfocytowa

Inclusion Criteria:

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

- Confirmed diagnosis of CLL/SLL and active disease clearly documented to have a need to initiate therapy.
- Has at least 1 marker of disease burden.
- Has an Eastern Cooperative Oncology Group (ECOG) performance status of 0 to 2 within 7 days before randomization.
- Has the ability to swallow and retain oral medication.
- Participants who are hepatitis B surface antigen (HBsAg) positive are eligible if they have received hepatitis B virus (HBV) antiviral therapy for at least 4 weeks and have undetectable HBV deoxyribonucleic acid (DNA) viral load before randomization.
- Participants with history of hepatitis C virus (HCV) infection are eligible if HCV ribonucleic acid (RNA) viral load is undetectable at screening.
- Participants with human immunodeficiency virus (HIV) who meet ALL eligibility criteria.

Exclusion Criteria:

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

- Has an active hepatitis B virus/ hepatitis C virus (HBV/HCV) infection.
- Has gastrointestinal (GI) dysfunction that may affect drug absorption.
- Has diagnosis of Richter Transformation or active central nervous system (CNS) involvement by CLL/SLL.
- Has had acquired immune deficiency syndrome (AIDS)-defining opportunistic infection in the past 12 months before screening.
- Has clinically significant cardiovascular disease.
- Has hypersensitivity to nemtabrutinib or contraindication to ibrutinib or acalabrutinib, or any of the excipients.
- Has history of severe bleeding disorder.
- Has history of second malignancy, unless potentially curative treatment has been completed with no evidence of malignancy for 2 years.
- Has received any systemic anticancer therapy for CLL/SLL.
- Is currently being treated with p-glycoprotein (P-gp) substrates with a narrow therapeutic index, cytochrome P450 3A (CYP3A) strong or moderate inducers or CYP3A strong inhibitors.
- Received prior radiotherapy within 2 weeks of start of study intervention, or radiation-related toxicities, requiring corticosteroids.
- Received a live or live-attenuated vaccine within 30 days before the first dose of study intervention. Administration of killed vaccines are allowed.
- Has received an investigational agent or has used an investigational device within 4 weeks before study intervention administration.
- Has active infection requiring systemic therapy.
- Participants who have not adequately recovered from major surgery or have ongoing surgical complications.