A Study of Nemtabrutinib (MK-1026) Versus Comparator (Investigator's Choice of Ibrutinib or Acalabrutinib) in First Line (1L) Chronic Lymphocytic Leukemia (CLL)/ Small Lymphocytic Lymphoma (SLL) (MK-1026-011/BELLWAVE-011)

Status: RECRUITING

Eligibility Criteria

Age: 18 years and over

This study is NOT accepting healthy

Healthy Volunteers: volunteers

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 known additional malignancy that is progressing or has required active treatment within the past 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, including intravenous (IV) antibiotics during screening. * Participants who have not adequately recovered from major surgery or have ongoing surgical complications.

Conditions & Interventions

Interventions:
DRUG: Nemtabrutinib, DRUG: Ibrutinib, DRUG: Acalabrutinib
Conditions:
Chronic Lymphocytic Leukemia, Small Lymphocytic Lymphoma

More Information

Contact(s): Toll Free Number - Trialsites@msd.com
Principal Investigator:
Phase: PHASE3
IRB
Number:
System ID: NCT06136559
