

# 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:

IRB

Number:

System ID: NCT06136559

Thank you for choosing StudyFinder. Please visit <http://studyfinder.ccr.vcu.edu> to find a Study which is right for you and contact [ctrrecruit@vcu.edu](mailto:ctrrecruit@vcu.edu) if you have questions or need assistance.