Venetoclax is being codeveloped by AbbVie and Genentech, a member of the Roche Group.

To learn more about these studies, please visit https://ClinicalTrials.gov or email abbvieclinicaltrials@abbvie.com

Key Inclusion Criteria

- Pathologically confirmed MCL (in tumor tissue), with documentation of either overexpression of cyclin D1 in association with other relevant markers (eg, CD19, CD20, PAX5, CD5) or evidence of t(11;14) as assessed by cytogenetics, fluorescent in situ hybridization (FISH), or polymerase chain reaction (PCR)
- At least 1 measurable site of disease on cross-sectional imaging (CT/PET)
- At least 1, but no more than 5, prior treatment regimens for MCL
- Failure to achieve at least partial response (PR) with, or documented disease progression after, the most recent treatment regimen
- Subjects must have adequate fresh or paraffin embedded tissue

Key Exclusion Criteria

- History or current evidence of central nervous system lymphoma
- Concurrent enrollment in another therapeutic investigational study or prior therapy with ibrutinib or other BTK inhibitors
- Prior treatment with venetoclax or other BCL2 inhibitors

Primary Outcome Measure

- Occurrence of TLS and DLTs
- To evaluate Progression-free survival (PFS) of ibrutinib and venetoclax compared to ibrutinib and placebo

Venetoclax and Ibrutinib are being investigated for indications that have not been approved by Regulatory Agencies. Safety and Efficacy have not been established in unapproved indications.


2. Specific doses information from study protocol, not in CT.gov

©2017 AbbVie Inc. North Chicago, IL 60064 A14543624 Aug 2017 Printed in U.S.A.