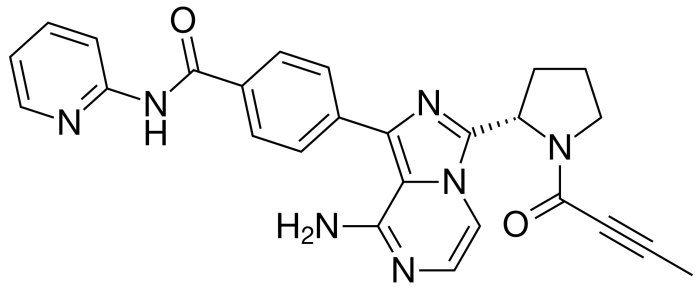
Brand Name: Calquence
Generic: acalabrutinib
Type: small molecule
Year Accepted/Phase: 2004

Mechanism:

Acalabrutinib inhibits BTK, a key enzyme in the B-cell receptor signaling pathway, which is critical for the survival and proliferation of malignant B cells.

Chemical Structure:



Indication:

Calquence is indicated for the treatment of mantle cell lymphoma (MCL) and chronic lymphocytic leukemia (CLL).

Clinical trials:

ACE-LY-004 Trial (Phase II)
Pubmed: https://pubmed.ncbi.nlm.nih.gov/29241979/
Purpose: Evaluate the efficacy and safety of acalabrutinib in patients with relapsed or refractory mantle cell lymphoma (MCL).
Dates: Conducted from 2014 to 2015.
Results: The ACE-LY-004 trial demonstrated that acalabrutinib had a high overall response rate (81%) and a favorable safety profile in patients with relapsed or refractory MCL.
Impact: These results supported the accelerated approval of acalabrutinib for the treatment of relapsed or refractory MCL by the FDA in 2017.

ELEVATE-TN Trial (Phase III)
Pubmed: https://pubmed.ncbi.nlm.nih.gov/32305093/
Purpose: Evaluate the efficacy and safety of acalabrutinib in combination with obinutuzumab or alone versus chlorambucil and obinutuzumab in treatment-naive patients with chronic lymphocytic leukemia (CLL).
Dates: Conducted from 2017 to 2019.
Results: The ELEVATE-TN trial showed that acalabrutinib, either alone or in combination with obinutuzumab, significantly improved progression-free survival (PFS) compared to chlorambucil and obinutuzumab in treatment-naive patients with CLL. Acalabrutinib also demonstrated a higher overall response rate and a favorable safety profile.
Impact: These results supported the approval of acalabrutinib for the first-line treatment of CLL by the FDA in 2019.

ASCEND Trial (Phase III)
Pubmed: https://pubmed.ncbi.nlm.nih.gov/32459600/
Purpose: Evaluate the efficacy and safety of acalabrutinib compared to investigator's choice of rituximab plus idelalisib or bendamustine in patients with relapsed or refractory CLL.
Dates: Conducted from 2015 to 2017.
Results: The ASCEND trial demonstrated that acalabrutinib significantly improved progression-free survival (PFS) compared to rituximab plus idelalisib or bendamustine in patients with relapsed or refractory CLL. Acalabrutinib also showed a higher overall response rate and a favorable safety profile.
Impact: These results supported the approval of acalabrutinib for the treatment of relapsed or refractory CLL by the FDA in 2019.