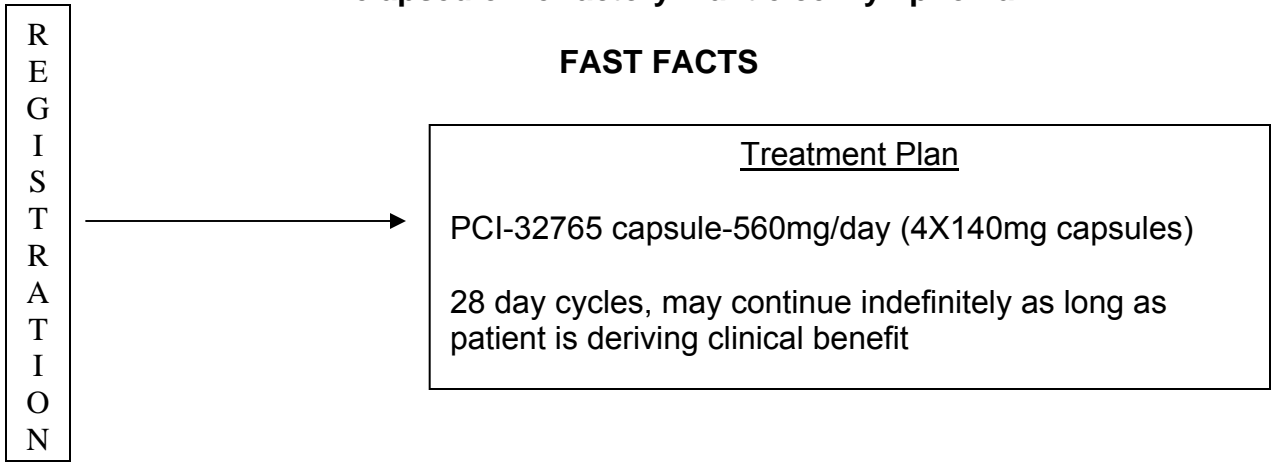


HO11402 A Phase II Study of Bruton's tyrosine kinase (BTK) inhibitor, PCI-32765, in relapsed or refractory mantle cell lymphoma



INCLUSION CRITERIA

- ECOG performance status of ≤ 2
- Pathologically confirmed MCL, with documentation of either overexpression of cyclin D1 or t(11;14), and measurable disease on cross sectional imaging that is ≥ 2 cm in the longest diameter and measurable in 2 perpendicular dimensions
- Documented failure to achieve at least PR with, or documented disease progression after, the most recent treatment regimen
- At least 1, but no more than 5 prior treatments for MCL.
 - Subjects having received > 2 cycles of bortezomib will be considered bortezomib exposed.
- Willing and able to swallow capsules without difficulty
- Ability to understand purpose and risk of study and signing informed consent.

EXCLUSION CRITERIA

- Prior chemotherapy within 3 weeks, nitrosoureas within 6 weeks, therapeutic anticancer antibodies within 4 weeks, radio- or toxin-immunoconjugates within 10 weeks, radiation therapy within 3 weeks, or major surgery within 2 weeks of first dose of study drug
- Concurrent enrollment in another investigational agent or previous exposure to PCI-32765
- History of other malignancies w/l the past year except for basal, squamous cell or in situ cervical cancer.
- Known CNS lymphoma
- Clinically significant cardiovascular disease within 6 months of screening, or any Class 3 or 4 cardiac disease
- Significant screening ECG abnormalities including QTc ≥ 500 msec
- Malabsorption syndrome or disease affecting GI function
- Know history of HIV, active infection with HCV or HBV, or any uncontrolled active systemic infection
- Will not agree to use highly effective contraception
- Labs:
 - ANC < 750 cells/uL (unless documented BM involvement,
 - platelets $< 50,000$ /uL,
 - AST and ALT $\geq 3 \times$ ULN,
 - creatinine $> 2.0 \times$ ULN

SCREENING ASSESSMENTS 21 days before start of drug:

- PET **AND** contrast CT chest, abdomen, pelvis ≤ 30 days of 1st dose.
- Bone Marrow Biopsy w/i 30 days. BM done w/l 60 days ok as long as after last prior therapy
- EKG in triplicate
- EORTC QOL
- CBC, CMP, LDH, Mg, Phosphate, uric acid, UA, HCG.