

A Multicenter Trial Available for Relapsed or Refractory Mantle Cell Lymphoma (MCL)

Multicenter Phase II Study of Bruton's Tyrosine Kinase (Btk) Inhibitor, PCI-32765, in Relapsed or Refractory Mantle Cell Lymphoma (MCL)

Objective:

- To evaluate the efficacy of PCI-32765 in relapsed/refractory subjects with Mantle cell lymphoma (MCL)
- To evaluate the safety of a fixed daily dosing regimen of PCI-32765 capsules in this population

Eligibility Criteria:

- ≥ 18 years of age
- Pathologically confirmed MCL, with documentation of either overexpression of cyclin D1 or t(11;14), and measurable disease
- 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 treatment regimens for MCL



Procedures:

- Physical exam, hematology, ECG, CT scans, PET scan and BMA done at screening
- Optional PK, PD, and PGt blood samples drawn during cycle 1
- Return weekly for 4 weeks and then monthly
- Survey will be done at screening and every 3 cycles thereafter

Benefits for Patients:

- Patients with up to 5 lines of prior therapy can be recruited
- Patients can remain on study as long as they show benefit
- The study is a non-randomized trial
- For patients who live more than 50 miles from MD Anderson, travel reimbursement might be available through the study sponsor

Protocol #2010-0837

Principal Investigator: Michael Wang, MD

Schedule an appointment or make referral online at <https://my.mdanderson.org> or call 713-745-5640

For more information about the study, contact PI, Michael Wang, MD, at 713-320-5264, or miwang@mdanderson.org, or Senior Research Nurse, Maria Badillo, RN, Lymphoma/Myeloma, at 713-745-2714 or mrbadill@mdanderson.org

For information on related articles or references for this study, visit <http://physicianrelations.org> or <http://clinicaltrials.gov/ct2/show/NCT01236391>

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