

MC0888: A Phase II Trial of cdk Inhibitor SCH727965 in Multiple Myeloma

Treatment
1 cycle = 21 days

- SCH727965 MTD IV once every three week cycle

MAJOR ELIGIBILITY CRITERIA:

- Patients must have relapsed or refractory Multiple Myeloma
- Patients must have measurable disease:
 - Measurable disease requires either 1g/dL serum M-spike, 200mg/24 hour urine M-spike
 - Patients with non-secretory disease may be eligible with elevated free light chains ($\geq 10\text{mg/dL}$) and abnormal free light chain ratio
- ≤ 5 prior therapies (stem cell transplant and preceding induction therapy counts as one therapy)
- Patient must be willing to submit blood and bone marrow samples for research component
- Must have adequate marrow function as indicated by Hgb $> 8\text{g/dL}$, platelets $> 75,000\text{cells/mm}^3$, ANC $> 1,000\text{cells/mm}^3$
- Normal organ function as indicated by creatinine $< 2.5\text{mg/dL}$; AST and ALT $\leq 2.5\text{X ULN}$, normal bilirubin
- Must not have other active malignancy or infection or uncontrolled psychiatric illness/social situation
- Age ≥ 18 years with an ECOG performance status of 0, 1, or 2.
- Must not be taking inhibitors or inducers of CYP3A4.
- Patients of childbearing potential must agree to use adequate contraception prior to study entry. Women must not be pregnant or breastfeeding

PRE-STUDY LABS AND TESTS:

- ≤ 28 days prior to randomization: Skeletal survey, Chest X-ray, PT, INR, LD, B2M, CRP, Immunofixations, urinalysis, bone marrow biopsy with cytogenetics and FISH
- ≤ 14 days prior to randomization: CBC w/ differential, glucose, electrolytes, creatinine, calcium, alk phos, AST, ALT, direct bilirubin, total bilirubin, uric acid, phosphorous, TSH, SPEP, UPEP, serum free light chains, immunoglobulins, serum pregnancy test, EKG

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