HO10408: A phase II, multi-center, non-randomized, open-label study of TKI258 in patients with relapsed or refractory multiple myeloma, who are with or without t(4;14) translocation

1 treatment cycle = 28 days

TKI258 500 mg/day P.O.
days 1-5, 8-12, 15-19, 22-26

Dex 40 mg P.O. days 1, 8, 15, 22
added only after PD on single agent TKI258

MAJOR ELIGIBILITY CRITERIA:

- Patients must have relapsed or refractory multiple myeloma with at least 2 prior therapy regimes
- Measurable disease requires either 1g/dL serum M-spike or 200 mg/24 hour urine M-spike
- Age ≥18 years with a ECOG performance status of ≤2
- Must NOT be receiving anticoagulation treatment with therapeutic doses of warfarin due to possible CYP1A1/2 interactions.
- Patients of childbearing potential must agree to use adequate contraception prior to study entry. Women must not be pregnant or breastfeeding.
- Patients must be willing to undergo additional bone marrow biopsy at Cycle 1, day 26.
- Must have the following baseline lab values:

♦ ANC ≥1,000/mm^3	♦ Serum creatinine ≤2.0 x ULN	♦ Hemoglobin ≥8 g/dL
♦ AST and ALT ≤3.0 x ULN	♦ Serum bilirubin ≤1.5 x ULN	♦ Platelets ≥75,000/mm^3

If marrow involvement, platelet >50K and ANC >750 OK for study

PRE-STUDY LABS AND TESTS:

- ≤28 days prior to registration: Skeletal survey/soft tissue plasmacytoma evaluation, chest X-ray, 12-lead ECG, MUGA or ECHO, cardiac enzymes, bone marrow biopsy, FISH analysis and plasma cell count.
- ≤14 days prior to registration: Hematology, coagulation and chemistry labs (to be done centrally, see Coordinator for details), SPEP, UPEP, fasting lipid panel, serum pregnancy test (if applicable), urinalysis.

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Based on Am3 (25Feb11)