Supplemental data file

Criteria for adequate organ function

- Adequate bone marrow function was defined as:
    - absolute neutrophil count (neutrophil and bands) ≥2,000 cells/mm^3
    - platelet count ≥125,000 cells/mm^3
    - hemoglobin ≥9.0 g/dl
- Adequate hepatic function was defined as:
    - total bilirubin ≤1.5 times the institutional upper limit of normal (ULN)
    - alanine aminotransferase (ALT) and aspartate aminotransferase (AST) ≤2.0 times the institutional ULN
- Adequate renal function was defined as:
    - serum creatinine ≤1.5 times the institutional ULN

Laboratory Test Assessments

Hematology, coagulation, CD4+ counts, creatine Kinase (CK)/CK-MB, troponin I and/or T, serum chemistry, bleeding time or platelet aggregometry, and urine analysis (along with a pregnancy test) were obtained to assess the patient's safety.

- Hematology (complete blood count (CBC), differential and platelets) were obtained pre-treatment, twice weekly for the first 4 weeks of treatment (generally on Day 1 and Day 5 ±2 days of each week), and then weekly from Weeks 5 - 12.
- CK, CK-MB, troponin I and troponin T were obtained pretreatment and then weekly for the first 12 weeks of treatment (if both troponin I and troponin T were unavailable at a center, performing just one troponin test was acceptable).

- A bleeding time measurement or platelet aggregometry was obtained prior to starting study drug (between Day -3 to predose, Day 1 of the first cycle), and approximately one hour after dosing on Day 12 of Cycle 1.
- Coagulation data (prothrombin pime [PT] and international normalized ratio [INR], and partial thromboplastin time [PTT]) was obtained pre-study, twice weekly for the first 4 weeks of treatment and weekly from Weeks 5 - 12.
- CD4+ T cell counts were obtained pre-treatment, twice weekly for the first 4 weeks of treatment and weekly from Weeks 5 - 12.
- Serum chemistry tests included lactate dehydrogenase (LDH), glucose, total protein, albumin, blood urea nitrogen (BUN), creatinine, alanine aminotransferase (ALT), aspartate aminotransferase (AST), alkaline phosphatase, total bilirubin, magnesium, sodium, potassium, chloride, bicarbonate, total serum calcium or ionized calcium, phosphorus, and uric acid. Serum Chemistry panels were obtained pretreatment, then weekly for the first 12 weeks on-treatment.
- A fasting cholesterol, triglyceride, and glucose was obtained pretreatment, and then repeated every 4 weeks.
- Thyroid-stimulating hormone (TSH) was obtained pretreatment and on Day 1 of Cycle 2.
- Urine Analysis: Dipstick and microscopic analysis was obtained pretreatment, and then repeated weekly for the first 12 weeks on-treatment.
- A chest x-ray was obtained at baseline.
- For women of child-bearing potential, a negative serum or urine pregnancy test (minimum sensitivity 25 IU/L or equivalent units of β-human chorionic gonadotropin [HCG]) was documented within 72 hours prior to start of treatment with study drug, and repeated after every 2nd cycle.

- All laboratory assessments were performed at the end of treatment visit.