



## CLINICAL TRIAL FACT SHEET

### “UPFRONT” VELCADE

#### **Randomized Phase IIIb study in previously untreated multiple myeloma patients:**

VELCADE, thalidomide, and dexamethasone (VTD) versus VELCADE and dexamethasone (VD) versus VELCADE, melphalan and prednisone (VMP)

**Trial description:** This is a three-arm, randomized trial for patients who have not been treated for myeloma and who are not candidates for high-dose chemotherapy and stem cell transplant. Patients will be randomly assigned to receive one of three treatments (VTD, VD, or VMP). Patients will know which therapy they’re receiving.

The study will include a screening period to determine eligibility for the study (4 weeks or less); an induction treatment period (approximately 6 months); a maintenance treatment period (approximately 6 months); and a post-treatment follow-up period.

**Trial objectives:** To compare the efficacy and safety of the three regimens.

#### **Eligibility:**

##### **Inclusion criteria:**

- 18 years or older
- Not a candidate for high-dose therapy with stem cell transplant
- Adequate ability to perform acts of daily living
- Symptomatic myeloma with measurable disease

##### **Exclusion criteria:**

- Diagnosis of smoldering myeloma, MGUS, or Waldenstrom’s macroglobulinemia
- Previously or currently treated with any other therapy for multiple myeloma
- Radiation therapy within 2 weeks before randomization
- Major surgery within 30 days before randomization (kyphoplasty is not major surgery)
- Allergy to any of the study medications or their analogs
- Greater than or equal to Grade 2 peripheral neuropathy
- For laboratory value requirements, visit the following National Cancer Institute site:  
<http://www.cancer.gov/search/ViewClinicalTrials.aspx?cdrid=561707&protocolsearchid=4549012&version=patient>

#### **Contacts and Locations:**

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