

# “STORM” CLINICAL TRIAL FACT SHEET

clinicaltrials.gov Identifier: NCT02336815

## A Phase 2b, Open-Label, Single-Arm Study of Selinexor (KPT-330) Plus Low-Dose Dexamethasone (Sd) in Patients with Multiple Myeloma Previously Treated with Lenalidomide, Pomalidomide, Bortezomib, Carfilzomib, and Daratumumab, and Refractory to Prior Treatment with Glucocorticoids, an Immunomodulatory Agent, a Proteasome Inhibitor, and the anti-CD38 mAb Daratumumab

**Trial Description:** This trial is for heavily pretreated myeloma patients with relapsed, refractory disease. Patients must have had previous treatment with the proteasome inhibitors Velcade® (bortezomib) and Kyprolis® (carfilzomib); the immunomodulatory agents Revlimid® (lenalidomide) and Pomalyst® (pomalidomide); and the anti-CD38 monoclonal antibody, Darzalex® (daratumumab). Patients must have disease that progressed during, or within 60 days after completing, therapy with steroids (dexamethasone, prednisone, or methylprednisolone), an immunomodulatory agent, a proteasome inhibitor, and an anti-CD38 monoclonal antibody.

Selinexor is a novel, first-in-class, orally administered “Selective Inhibitor of Nuclear Export” (SINE™) compound. Selinexor blocks the ability of cancer cells to pump out, or export, tumor suppressor proteins from their cell nuclei. This restores the tumor suppressor proteins’ ability to detect cancerous DNA changes and cause cancer cell death. Selinexor also reduces levels of key proteins that promote cancer cell growth.

The most common side effects of selinexor include nausea, fatigue, weight loss, vomiting, diarrhea and low blood cell counts.

**Trial Objectives:** To determine the overall response rate and the duration of response to selinexor + dexamethasone in myeloma patients who have been exposed to an immunomodulatory agent, a proteasome inhibitor, and the anti-CD38 monoclonal antibody Darzalex, and who are refractory to these classes of drugs (“penta-refractory”).

**Trial Design:** All patients will receive 80 mg of oral selinexor plus 20 mg of oral dexamethasone twice weekly (i.e., Monday and Wednesday or Tuesday and Thursday) in each four-week cycle.

**Duration of Treatment:** Patients will receive treatment until their myeloma progresses or until they are unable to tolerate the regimen. Patients may decide not to participate and withdraw their consent at any time, for any reason.

**Other Medications:** All patients will receive medications to reduce nausea during the trial. Other medications may be given as needed to help reduce side effects. Patients may continue to take medications that they need to treat pre-existing diseases like diabetes, high blood pressure, etc. Patients will not be able to take any other anti-cancer therapy or any other experimental agents while they are participating in this trial.

**Eligibility Criteria:** Myeloma patients age 18 or older must have one of the following:

- Measurable myeloma based on International Myeloma Working Group (IMWG) guidelines. Patients must have measurable disease as defined by at least one of the following:
  - Serum M-protein of at least 0.5 g/dL
  - Urinary M-protein of at least 200 mg/24 hours
  - Free light chain (FLC) assay result of at least 100 mg/L, provided that the FLC ratio is abnormal
- Participants must have previously received at least 3 anti-myeloma regimens including: an alkylating agent (for example, melphalan or cyclophosphamide), Revlimid, Pomalyst, Velcade, Kyprolis, Darzalex, and a glucocorticoid (for example, dexamethasone, prednisone, or methylprednisolone). There is no upper limit on the number of prior therapies, provided that all other inclusion/exclusion criteria are met.
- Participants must have myeloma that is refractory to previous treatment with steroids, an immunomodulatory agent, a proteasome inhibitor, and an anti-CD38 monoclonal antibody. “Refractory” is defined as a 25% or less response to therapy, or progression within 60 days after completing therapy.

**Exclusion Criteria:**

- Smoldering multiple myeloma
- Plasma cell leukemia
- Documented systemic amyloid light chain (AL) amyloidosis
- Active myeloma in the central nervous system

## Locations Enrolling Patients and Contact Information:

Choosing to participate in a clinical trial is an important personal decision. Talk with your doctor, family members, and friends about deciding to join a study.

To learn more about this study, you or your doctor may contact the study research staff. Please refer to this study by its [clinicaltrials.gov](https://clinicaltrials.gov) identifier, **NCT02336815**.

New sites will be opening in the coming weeks and months. Please check current site status on the [clinicaltrials.gov](https://clinicaltrials.gov) website using its identifier, **NCT02336815**.

### *Alabama*

University of Alabama  
Birmingham, AL  
Contact: Luciano Costa, MD; 800-822-8816

### *Arizona*

Mayo Clinic  
Scottsdale, AZ  
Contact: Keith Stewart, MD; 855-776-0015

### *California*

UCLA Jonsson Comprehensive Cancer Center  
Los Angeles, CA  
Contact: Gary Schiller, MD, PhD; 888-798-0719

### *Connecticut*

Yale University Hospital  
New Haven, CT  
Contact: Terry Lynn Parker, MD; 203-688-4242

### *Florida*

H. Lee Moffitt Cancer Center Research Institute  
Tampa, FL  
Contact: Rachid Baz, MD; 888-663-3488  
University of Miami Sylvester Cancer Center  
Miami, FL  
Contact: James Hoffman, MD; 305-243-1000

### *Georgia*

Winship Cancer Institute, Emory University  
Atlanta, GA  
Contact: Ajay Nooka, MD; 404-778-1868

### *Illinois*

University of Chicago Medical Center  
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### *Indiana*

IU Simon Cancer Center  
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Contact: Rafat Abonour, MD; 888-600-4822

### *Maryland*

Johns Hopkins  
Baltimore, MD  
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### *Massachusetts*

Dana-Farber Cancer Institute  
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### *Michigan*

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### *Minnesota*

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### *Missouri*

Washington University St. Louis  
St. Louis, MO  
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### *New Jersey*

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### *New York*

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Mount Sinai Medical Center  
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Contact: Sundar Jagannath, MD; 212-241-6500

### *Pennsylvania*

Abramson Cancer Center of the University of Pennsylvania  
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Contact: Dan Vogl, MD; 800-789-7366

### *Tennessee*

Vanderbilt University Ingram Cancer Center  
Nashville, TN  
Contact: Robert Cornell, MD; 800-811-8480

### *Texas*

Baylor University Medical Center  
Dallas, TX  
Contact: Moshe Levy, MD; 214-370-1000

### *Washington*

Swedish Cancer Center  
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