

# RESEARCH STUDY

WCMC

IRB APPROVED

Approved:

06-08-2010

Expires:

04-11-2011

## Disease

Autoimmune Kidney Disease

## Protocol Title: "Velcade® Therapy for Proliferative Lupus Nephritis"

IRB # 1003010960

## Principal Investigator/Contact Information

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## Study Status

Recruiting

## Brief Summary of Protocol

The purpose of this study is to determine what effects, good or bad, Velcade can have on patients with severe proliferative lupus nephritis (LN), an inflammation of the kidney caused by systemic lupus erythematosus (SLE). Velcade is approved by the United States Food and Drug Administration (FDA) for the treatment of multiple myeloma, a cancer of plasma cells, but it can also act on non-cancerous normal plasma cells that produce abnormal antibody proteins. Studies that were done in the past have suggested that Velcade may interfere with pathways leading to inflammation in the kidney.

Patients eligible for this study will be male or female, 18 years old or more, with biopsy-proven lupus nephritis (WHO class III or IV or V), chronic kidney disease stage 3 or more with creatinine clearance greater or equal to 30 cc/min/1.73m<sup>2</sup>, and presence of protein in the urine. They cannot have serious medical conditions and infections, such as HIV, hepatitis B or C, a history of an untreated positive tuberculosis skin test, or cancer within the past 3 years. Additional criteria are also considered, including laboratory tests to be done during the screening phase of the study.

Once eligibility is confirmed, the study will involve 3 cycles of Velcade therapy, which will be given through a vein in a series of 4 visits per cycle, each visit separated by 72 hours. Each cycle will occur at approximately 1-month intervals, with follow-up visits in between cycles and after the last cycle.

The total duration of the study will be 1 year.

Study visits will take place at the New York Hospital/Weill Cornell Medical Center Clinical and Translational Science Center (CTSC) outpatient unit and at The Rogosin Institute Outpatient Clinic. Blood and urine will be collected at most visits, and the study doctors will monitor all the medications taken, regardless of their indication.

Millennium Pharmaceuticals, Inc. is the company manufacturing Velcade. Millennium will be providing the medication throughout the study, but is not considered the sponsor.

## Treatment Overview (Potential Benefits)

There may or may not be direct benefits to participants. Kidney disease may or may not improve during the study. However, information collected may contribute to the future care of patients with severe lupus nephritis.

## IRB Information

Weill Cornell Medical Center IRB

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