CLINICAL TRIAL FACT SHEET

Clinicaltrials.gov Identifier: NCT01850524

Ixazomib Plus Lenalidomide and Dexamethasone Versus Placebo Plus Lenalidomide and Dexamethasone in Adult Patients with Newly Diagnosed Myeloma

Trial Description: A phase III multicenter study in which patients are randomly assigned by a computer to receive either a placebo (a capsule that looks like ixazomib but has no active ingredient) plus lenalidomide and dexamethasone, or ixazomib (an oral proteasome inhibitor) plus lenalidomide and dexamethasone. This is a double-blind study, meaning that neither the patient, nor the caregiver, nor the doctor, nor those who evaluate the trial outcome know which treatment regimen the patient is receiving. This trial is for patients with newly diagnosed myeloma who are not eligible for stem cell transplant.

Trial Objectives: To determine progression-free survival (PFS), defined as the time from the date a patient is randomized to the date that disease progression (relapse) is first documented. Secondary objectives are to determine the length of time it takes for patients to reach a complete response (CR) and to determine overall survival (OS) rates over a period of five years.

Trial Arms:

- **Arm 1 (active comparator arm)**

  Ixazomib + lenalidomide (Revlimid) + dexamethasone Patients will receive an oral dose of ixazomib (4 mg) on days 1, 8, and 15; an oral dose of lenalidomide (25 mg) on days 1–21; and an oral dose of dexamethasone (40 mg) on days 1, 8, 15, and 22 every 28 days.

- **Arm 2 (placebo comparator arm)**

  Placebo + lenalidomide + dexamethasone Patients will receive an oral dose of placebo on days 1, 8, and 15; an oral dose of lenalidomide (25 mg) on days 1–21; and an oral dose of dexamethasone (40 mg) on days 1, 8, 15, and 22 every 28 days.

- **Other requirements:** The time commitment for this study is up to 24 months. Participants will be required to make 28 visits to the clinic where they are being treated during the treatment period, and will continue to make follow-up visits every four weeks until the next line of therapy begins. Participants will also be contacted by telephone every 12 weeks after the last treatment visit for a follow-up assessment.

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International Myeloma Foundation

International Myeloma Foundation
12650 Riverside Drive, Suite 206, North Hollywood, CA 91607 USA
Telephone: 800-452-CURE (2873) (USA & Canada) 818-487-7455 (worldwide) • TheIMF@myeloma.org • myeloma.org

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Key Eligibility Criteria:

- Patients must be at least 18 years old, have a confirmed diagnosis of myeloma, and have not received prior treatment for myeloma.
- Lenalidomide + dexamethasone must be appropriate treatment for the patient, and the patient must be ineligible for transplant either because he or she is older than 65 years, or if younger, must have another condition that would make high-dose therapy with stem cell rescue an inappropriate procedure.
- Patients must meet the clinical laboratory criteria set forth in the treatment protocol.
- Female patients must be post-menopausal, or must be surgically sterile, or must agree to practice true abstinence AND must adhere to the guidelines of the lenalidomide pregnancy prevention program.
- Patients must be able to take 70–325 mg of daily aspirin during the trial (or enoxaparin if allergic to aspirin) to prevent a blood clot.

Key exclusion criteria:

- Any prior treatment for myeloma.
- Diagnosed and treated for another cancer within 5 years of being randomized for this trial, or diagnosed with another cancer and have any evidence of residual disease. Patients with skin cancer other than melanoma or patients with carcinoma in situ are not disqualified if they have had a complete resection.
- Myeloma that involves the central nervous system.
- Female patients who are pregnant or lactating.
- Diagnosis of Waldenström's macroglobulinemia, POEMS syndrome, plasma cell leukemia, primary amyloidosis, myelodysplastic syndrome, or myeloproliferative syndrome.
- A current uncontrolled cardiovascular condition.
- Inability to swallow oral medications or a gastrointestinal procedure that could interfere with oral absorption or tolerance of treatment.
- Known infection with hepatitis B or C, or HIV positive.

(trial sites on next page)

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Sites that are or will be recruiting patients

(For the latest updates, contact the Takeda Study Registration Call Center at 877-825-3327 or medicalinformation@tpna.com)

USA

Alabama
Birmingham

Arizona
Chandler
Tucson

Arkansas
Little Rock (not yet recruiting)

California
Anaheim
Fountain Valley
La Jolla
Mission Hills
Riverside (not yet recruiting)
San Diego (not yet recruiting)
San Leandro (not yet recruiting)
Vallejo

Colorado
Denver

Connecticut
Southington

Florida
Jacksonville
Miami
Miami Beach
West Palm Beach

Georgia
Marietta

Hawaii
Honolulu (not yet recruiting)

Iowa
Iowa City (not yet recruiting)

Kansas
Westwood

Kentucky
Lexington
Louisville

Louisiana
Lexington (not yet recruiting)
Shreveport

Maryland
Baltimore
Towson

Massachusetts
Boston
Burlington (not yet recruiting)
Worcester (not yet recruiting)

Michigan
Ann Arbor
Southfield

Minnesota
Chesterfield
Minneapolis
Missouri
Rochester

New Mexico
Albuquerque
Farmington
Las Cruces (not yet recruiting)

New York
Buffalo
Lake Success
New York
Poughkeepsie

Ohio
Cincinnati
Cleveland (not yet recruiting)
Columbus
Toledo

Oklahoma
Tulsa

Oregon
Portland

Pennsylvania
Hershey
Pittsburgh

South Carolina
Charleston

Tennessee
Cookeville
Knoxville

Texas
Austin
Galveston
Temple
Tyler

Vermont
Burlington

Virginia
Richmond (not yet recruiting)
Salem

Washington
Spokane
Vancouver

CANADA

Alberta
Calgary
Edmonton

British Columbia
Abbotsford
Surrey
Victoria (not yet recruiting)

New Brunswick
St. John

Ontario
Hamilton
London
Ottowa
Toronto

Nova Scotia
Halifax

Quebec
Levis (not yet recruiting)
Montreal
Sherbrooke

FRANCE

Amiens
Angers
Bayonne
Bordeaux
Bourg-en-Bresse (not yet recruiting)
Brest (not yet recruiting)
Caen
Chalon Sur Saone
Clamart
Créteil
Dunkerque
La Roche Sur Yon
La Tronche
Le Chesnay-Versailles
Le Mans
Lens
Lille
Limoges
Montivilliers
Montpellier
Mulhouse
Nantes
Nice
Paris
Perigueux
Pessac
Poitiers
Pontoise
Reims
Rennes
Rouen
Saint-brieuc
Saint-priest En Jarez
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Tours
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Vannes

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