

# CLINICAL TRIAL FACT SHEET

Clinicaltrials.gov Identifier: NCT02181413

## A Study of Oral Ixazomib Citrate (MLN9708) Maintenance Therapy in Patients with Multiple Myeloma Following Autologous Stem Cell Transplant

**Trial Description:** In this phase III study, patients who have had any type of positive response to induction therapy followed by high-dose therapy with stem cell transplant will be randomly assigned by a computer to receive either a placebo (a capsule that looks like ixazomib but has no active ingredient) or ixazomib, an oral proteasome inhibitor, as maintenance therapy. 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 if the patient is receiving ixazomib or placebo.

**Trial Objectives:** To determine the effect of ixazomib maintenance therapy on progression-free survival (PFS), defined as the time from the date a patient is randomized to the date that disease progression is first documented, compared to placebo. Key secondary objectives including determining 1) overall survival (OS) rates for a period of up to 110 months; 2) time to disease progression; 3) time to the end of the next line of therapy; 4) time to the second disease progression; 5) time to the end of the next line of therapy after the study treatment; 6) duration of the next line of therapy after the study treatment; 7) percentage of patients who develop a new primary malignancy; 8) percentage of participants who convert from minimal residual disease (MRD) positive to MRD negative; 9) correlation of MRD status with PFS and OS; and 10) percentage of participants with adverse events (AEs, or unfavorable and unintended signs or symptoms associated with ixazomib or placebo).

### Trial Arms:

- **Arm 1 (experimental arm)**

**Cycles 1 through 4:** Ixazomib 3 mg capsule orally, once daily, on days 1, 8, and 15 of a 28-day cycle.

**Cycles 5–26:** Ixazomib 3 or 4 mg capsule orally, once daily, on days 1, 8, and 15 of a 28-day cycle.

Patients experiencing AEs attributed to the study drug during any cycle may continue in the study but may have doses of the study drug held or reduced by at least one dose level.

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

**Cycles 1 through 4:** Placebo capsule matching the 3 mg ixazomib capsule orally, once daily, on days 1, 8, and 15 of a 28-day cycle.

**Cycles 5–26:** Placebo capsule matching the 3 mg or 4 mg ixazomib capsule orally, once daily, on days 1, 8, and 15 of a 28-day cycle.

Patients experiencing AEs attributed to the study drug during any cycle may continue in the study but may have doses of the study drug held or reduced by at least one dose level.

- **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**

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### Key Eligibility Criteria:

- Documented evidence of cytogenetics and FISH testing obtained at any time before transplant, and ISS staging at the time of diagnosis.
- Induction therapy must have been standard of care and have included a proteasome inhibitor (PI) and/or an immunomodulating drug (IMiD) followed by a single autologous stem cell transplant with high-dose melphalan conditioning, within 12 months of diagnosis. VAD is not an acceptable induction therapy for this trial.
- Cannot have started screening for the trial before 75 days after transplant and cannot be randomized for the trial later than 115 days after transplant.
- No post-ASCT consolidation therapy.
- Documented response to ASCT of at least PR (50% drop in monoclonal protein) according to IMWG criteria.
- Female patients of childbearing potential must, from the time they sign a consent form until 90 days after they have their last dose of study drug, practice 2 effective, acceptable methods of contraception at the same time.
- Male patients, even post vasectomy, must practice effective barrier contraception from the time of signing the consent form until 90 days after their last dose of study drug.

### Key Exclusion Criteria:

- Multiple myeloma that has relapsed following primary therapy or did not respond to primary therapy. For this study, stable disease after stem cell transplant is considered non-responsive to primary therapy.
- Tandem (double) transplant.
- Radiation therapy, major surgery, or infection requiring intravenous antibiotics within two weeks before randomization.
- Myeloma involvement in the central nervous system.
- Uncontrolled cardiovascular conditions, including uncontrolled hypertension, cardiac arrhythmias, congestive heart failure, or myocardial infarction within the past 6 months.
- Peripheral neuropathy that is Grade 1 with pain or Grade 2 or higher of any cause.
- Treatment with any investigational products within 60 days before the first dose of the study drug regimen.

*(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](mailto:medicalinformation@tpna.com))

#### USA

Morgantown, West Virginia  
(not yet recruiting)

#### AUSTRALIA

Adelaide (not yet recruiting)  
Auchenflower  
Heidelberg  
Kogarah (not yet recruiting)  
Pahran  
Waratah  
Woodville South (not yet recruiting)

#### AUSTRIA

Vienna

#### BELGIUM

Antwerp  
Brugge (not yet recruiting)  
Gent (not yet recruiting)  
La Louviere (not yet recruiting)

#### CZECH REPUBLIC

Brno (not yet recruiting)  
Hradec Kralove (not yet recruiting)  
Olomouc (not yet recruiting)  
Ostrava  
Praha 2  
Praha 10 (not yet recruiting)

#### DENMARK

Aalborg (not yet recruiting)  
Arhus C  
Copenhagen  
Herlev (not yet recruiting)  
Odense  
Roskilde  
Veijle (not yet recruiting)

#### FRANCE

Clamart (not yet recruiting)  
Lille (not yet recruiting)  
Nantes  
Paris

#### GERMANY

Berlin  
Bonn  
Darmstadt (not yet recruiting)  
Dresden  
Essen (not yet recruiting)  
Frankfurt Am Main (not yet recruiting)  
Hagen (not yet recruiting)  
Hamburg  
Hannover (not yet recruiting)  
Heidelberg  
Köln (not yet recruiting)  
Ludwigshafen (not yet recruiting)

#### Mainz

Mannheim  
München  
Oldenburg  
Tübingen  
Würzburg (not yet recruiting)

#### GREECE

Athens  
Thessaloniki (not yet recruiting)

#### HUNGARY

Budapest  
Debrecen (not yet recruiting)  
Kaposvar (not yet recruiting)  
Szeged

#### ISRAEL

Haifa (not yet recruiting)  
Jerusalem (not yet recruiting)  
Naharia (not yet recruiting)  
Petah-tiqwa (not yet recruiting)  
Ramat-gan (not yet recruiting)  
Rehovot (not yet recruiting)  
Safed (not yet recruiting)  
Tel Aviv (not yet recruiting)

#### ITALY

Ancona  
Bologna (not yet recruiting)  
Brescia (not yet recruiting)  
Firenze (not yet recruiting)  
Meldola (not yet recruiting)  
Milano (not yet recruiting)  
Rimini (not yet recruiting)  
Rionero in Vulture  
Roma (not yet recruiting)  
Terni (not yet recruiting)  
Torino (not yet recruiting)

#### KOREA, REPUBLIC OF

Daejeon (not yet recruiting)  
Goyang-SI  
Incheon  
Seoul

#### NETHERLANDS

Amsterdam  
Dordrecht (not yet recruiting)  
Groningen (not yet recruiting)  
Utrecht (not yet recruiting)

#### NORWAY

Gjettum (not yet recruiting)  
Oslo  
Stavanger (not yet recruiting)  
Trondheim (not yet recruiting)

#### POLAND

Brzozow (not yet recruiting)  
Chorzow (not yet recruiting)  
Lodz

#### PORTUGAL

Braga (not yet recruiting)  
Coimbra (not yet recruiting)  
Porto

#### SINGAPORE

Singapore

#### SOUTH AFRICA

Johannesburg  
Pretoria

#### SPAIN

Badalona  
Barcelona (not yet recruiting)  
Cordoba (not yet recruiting)  
Girona (not yet recruiting)  
Madrid  
Salamanca (not yet recruiting)  
Sevilla (not yet recruiting)

#### SWEDEN

Göteborg  
Helsingborg (not yet recruiting)  
Lund  
Stockholm  
Uppsala

#### TAIWAN

Kaohsiung (not yet recruiting)  
Taipei (not yet recruiting)  
Taoyuan County (not yet recruiting)

#### THAILAND

Bangkok

#### TURKEY

Ankara (not yet recruiting)

#### UNITED KINGDOM

Leeds (not yet recruiting)  
Leicester  
London (not yet recruiting)  
Oxford  
Sutton (not yet recruiting)  
Swansea (not yet recruiting)

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