ALICE* IS AN **ACTIVE ELDERLY**† PATIENT WITH MULTIPLE MYELOMA AT **FIRST RELAPSE**

AT THE FIRST MULTIPLE MYELOMA RELAPSE, OFFER DURABLE STRENGTH WITH THE NINLARO REGIMEN‡[1]

Learn about patients who could benefit from NINLARO at **NINLAROhcp.com**

*Hypothetical patient.
†Used herein to refer to patients aged 75 years or older.
‡The NINLARO regimen includes NINLARO + lenalidomide + dexamethasone.[1]

INDICATION AND USAGE

Indication: NINLARO is indicated in combination with lenalidomide and dexamethasone for the treatment of patients with multiple myeloma who have received at least one prior therapy.

Limitations of Use: NINLARO is not recommended for use in the maintenance setting or in newly diagnosed multiple myeloma in combination with lenalidomide and dexamethasone outside of controlled clinical trials.

IMPORTANT SAFETY INFORMATION

WARNINGS AND PRECAUTIONS

- **Thrombocytopenia** has been reported with NINLARO. Platelet nadirs typically occurred between Days 14-21 of each 28-day cycle and recovered to baseline by the start of the next cycle. Grade 3 thrombocytopenia was reported in 17% of patients in the NINLARO regimen and Grade 4 thrombocytopenia was reported in 13% in the NINLARO regimen. During treatment, monitor platelet counts at least monthly, and consider more frequent monitoring during the first three cycles. Manage thrombocytopenia with dose modifications and platelet transfusions as per standard medical guidelines.

Please see additional Important Safety Information throughout and NINLARO (ixazomib) full Prescribing Information.

NINLARO® (ixazomib) capsules
4mg | 3mg | 2.3mg

MEET **ALICE**, AN ACTIVE ELDERLY PATIENT **AT FIRST RELAPSE**

Alice is 75 years old. She is retired and enjoys spending time with her grandchildren, taking long walks in the countryside, and tending to her vegetable garden.

Hypothetical patient

- Alice has been living with multiple myeloma (MM) for 3.5 years
- She received a first-line anti-CD38 antibody-based regimen, followed by maintenance therapy
  - Alice is not lenalidomide refractory
- Following new symptoms, a clinic visit confirmed her MM had relapsed
- Like many others with MM, Alice is an active elderly patient
- Nearly 1 in 3 (30%)* patients experiencing their first MM relapse are aged 75 years or older[2]

Alice's next treatment choice is crucial.

"I am anxious about changing treatments because you just don't know what side effects you're going to face."

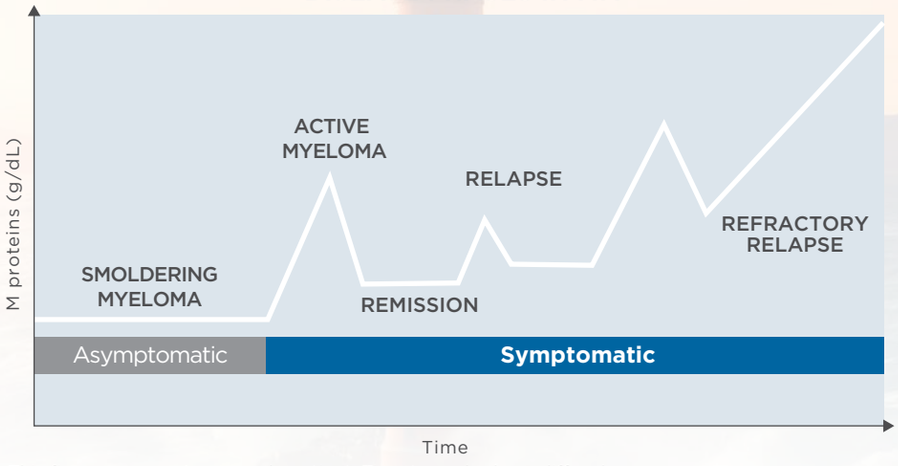
—A real patient similar to Alice

*Based on chart audits, 20,277 US MM patients per year experience their first relapse; 6,054 of these patients are elderly.[2]

Please see additional Important Safety Information throughout and NINLARO (ixazomib) full Prescribing Information.

AS OUTCOMES MAY WORSEN WITH INCREASING LINES OF THERAPY, THE FIRST RELAPSE IS A CRITICAL JUNCTURE IN THE MM TREATMENT JOURNEY[3,4]

DISEASE PHASES IN MM[5]



This figure represents a sample patient. Time to each phase differs by person.

ALICE'S GOALS

- Like many elderly cancer patients, Alice wants to maintain her independence[6]
- She wants a therapy that may allow her to live longer without her disease getting worse and without compromising her lifestyle
- An option with convenient dosing and manageable tolerability is important to her

Her doctor recommended a therapy that can:

- **Significantly delay disease progression[1]**
- **Fit into her lifestyle with the convenience of an all-oral triplet regimen*[1,7,8]**
- **Offer a generally tolerable safety profile[1,9]**

After shared decision-making with her oncologist, **Alice chose the NINLARO® (ixazomib) triplet regimen.*†**

WHAT ARE YOUR TREATMENT GOALS FOR AN ACTIVE ELDERLY PATIENT AT FIRST RELAPSE?

*The NINLARO regimen includes NINLARO + lenalidomide + dexamethasone.[1]

†Please see pages 6–9 to review efficacy, safety, and dosing information for NINLARO.

MM=multiple myeloma.

IMPORTANT SAFETY INFORMATION

WARNINGS AND PRECAUTIONS (cont'd)

- **Gastrointestinal Toxicities,** including diarrhea, constipation, nausea and vomiting were reported with NINLARO and may occasionally require the use of antidiarrheal and antiemetic medications, and supportive care. Diarrhea resulted in the discontinuation of one or more of the three drugs in 3% of patients in the NINLARO regimen and 2% of patients in the placebo regimen. Adjust dosing for Grade 3 or 4 symptoms.

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NEXT TIME YOU SEE A PATIENT LIKE ALICE, CONSIDER THE ALL-ORAL NINLARO® (ixazomib) TRIPLET REGIMEN*

ABOUT ALICE

Reason for clinic visit
- Patient had been experiencing new-onset back pain and generalized fatigue

Diagnosis
- Diagnosed with multiple myeloma 3.5 years ago; R-ISS stage I
- Patient had a history of hypertension

Treatment history
- Initially treated with an anti-CD38 antibody + immunomodulator + steroid
- Treated for 25 months; achieved best response of CR
- Treatment continued with an immunomodulator as maintenance therapy
- She is not lenalidomide refractory

Laboratory results
- **ECOG PS:** 1
- **Hemoglobin:** 9.5 g/dL
- **Serum creatinine:** 1.1 mg/dL
- **Serum calcium:** 10.5 mg/dL
- **Serum M protein:** 1.2 g/dL
- **Skeletal imaging:** one new lytic lesion
- **Cytogenetics/FISH:** negative for high-risk features

*The NINLARO regimen includes NINLARO + lenalidomide + dexamethasone.[1]

CR=complete response; ECOG PS=Eastern Cooperative Oncology Group performance status; FISH=fluorescence in situ hybridization; R-ISS=revised International Staging System.

Please see additional Important Safety Information throughout and accompanying NINLARO (ixazomib) full Prescribing Information.

ALICE'S TREATMENT JOURNEY

48% of elderly patients with MM receive doublet regimens.[2] With the NINLARO triplet regimen,* you can offer extended PFS, tolerability, and convenient dosing.[1]

Time

Alice was diagnosed with MM
R-ISS stage 1

Began first-line regimen
Treated with an anti-CD38 antibody + immunomodulator + steroid; achieved CR

Received maintenance therapy
Treatment continued with an immunomodulator as maintenance therapy

Relapse confirmed
Discussed second-line treatment goals with oncologist

Now receives the NINLARO regimen*†

"It's very convenient. I'm happy that I'm taking oral medication and I can take it anywhere."

—A real patient similar to Alice

*The NINLARO regimen includes NINLARO + lenalidomide + dexamethasone.[1]

†Please see pages 6–9 to review efficacy, safety, and dosing information for NINLARO.

CR=complete response; MM=multiple myeloma; PFS=progression-free survival; R-ISS=revised International Staging System.

IMPORTANT SAFETY INFORMATION

WARNINGS AND PRECAUTIONS (cont'd)

- **Peripheral Neuropathy** was reported with NINLARO. The most commonly reported reaction was peripheral sensory neuropathy (24% and 17% in the NINLARO and placebo regimens, respectively). Peripheral motor neuropathy was not commonly reported in either regimen (<1%). Peripheral neuropathy resulted in discontinuation of one or more of the three drugs in 4% of patients in the NINLARO regimen and <1% of patients in the placebo regimen. During treatment, monitor patients for symptoms of neuropathy and consider adjusting dosing for new or worsening peripheral neuropathy.

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Next time you see an active elderly patient at first relapse

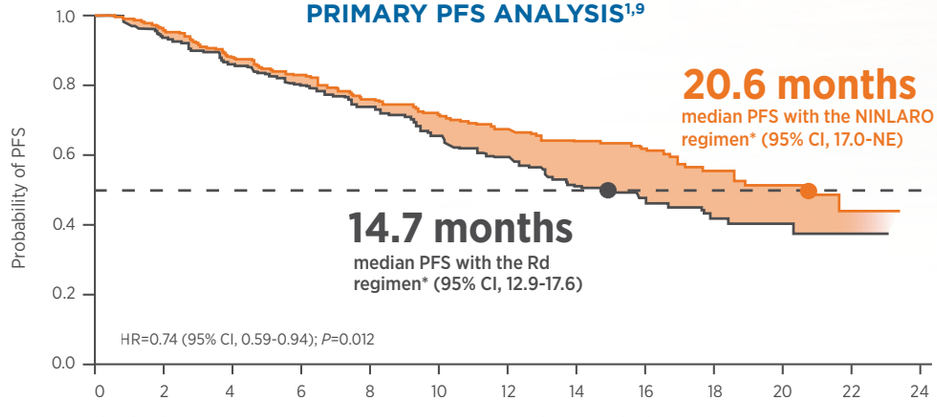
THE NINLARO® (ixazomib) REGIMEN PROLONGED PROGRESSION-FREE SURVIVAL VS THE Rd REGIMEN*

STUDY DESIGN

TOURMALINE-MM1 was a global, phase 3, randomized (1:1), double-blind, placebo-controlled study that evaluated the safety and efficacy of the NINLARO regimen* vs the Rd regimen* in 722 patients with relapsed and/or refractory multiple myeloma who received 1-3 prior therapies.[1,9,10]

- The primary endpoint of PFS, according to 2011 IMWG criteria, was assessed every 4 weeks until disease progression by a blinded IRC and was based on central laboratory results[1]
- Key secondary endpoints included OS and OS in del(17p)[9]
- Other select secondary endpoints included ORR, PFS in patients with high-risk cytogenetics,† and safety[9]
- Patients who were refractory to lenalidomide or PIs were excluded from the study[1]

PRIMARY PFS ANALYSIS[1,9]



Number of patients at risk

NINLARO regimen	360	332	298	270	233	206	145	111	72	44	26	9	0
Rd regimen	362	325	288	254	218	188	130	85	58	31	15	3	0

FINAL OS ANALYSIS[1]

- With a median follow-up of ~85 months, median OS in the ITT population was 53.6 months for patients receiving the NINLARO regimen* and 51.6 months for patients receiving the Rd regimen* (HR=0.94 [95% CI, 0.78-1.13])

*The NINLARO regimen included NINLARO + lenalidomide + dexamethasone. The Rd regimen included placebo + lenalidomide + dexamethasone.[1]

†Defined as patients with del(17p), t(4;14), and/or t(14;16).[9]

CI=confidence interval; HR=hazard ratio; IMWG=International Myeloma Working Group; IRC=independent review committee; ITT=intent-to-treat; NE=not evaluable; ORR=overall response rate; OS=overall survival; PFS=progression-free survival; PI=proteasome inhibitor.

IMPORTANT SAFETY INFORMATION

WARNINGS AND PRECAUTIONS (cont'd)

- **Peripheral Edema** was reported with NINLARO. Evaluate for underlying causes and provide supportive care, as necessary. Adjust dosing of NINLARO for Grade 3 or 4 symptoms or dexamethasone per its prescribing information.

Please see additional Important Safety Information throughout and NINLARO (ixazomib) full Prescribing Information.

In TOURMALINE-MM1

THE NINLARO REGIMEN* DEMONSTRATED A SAFETY PROFILE COMPARABLE TO THE Rd REGIMEN*[1]

NON-HEMATOLOGIC ARs OCCURRING IN ≥5% OF PATIENTS WITH A ≥5% DIFFERENCE BETWEEN NINLARO + Rd AND Rd IN TOURMALINE-MM1[1]

AR	NINLARO+Rd* (n=361)			Rd* (n=359)		
	All grades	Grade 3	Grade 4	All grades	Grade 3	Grade 4
Diarrhea	52%	10%	0	43%	3%	0
Constipation	35%	<1%	0	28%	<1%	0
Peripheral neuropathies†	32%	2%	0	24%	2%	0
Nausea	32%	2%	0	23%	0	0
Peripheral edema	27%	2%	0	21%	1%	0
Back pain‡	27%	<1%	0	24%	3%	0
Rash†	27%	3%	0	16%	2%	0
Upper respiratory tract infection‡	27%	1%	0	23%	1%	0
Vomiting	26%	1%	0	13%	<1%	0
Bronchitis	22%	2%	0	17%	2%	<1%

- Incidence of thrombocytopenia in patients in the NINLARO and Rd regimens,* respectively: any grade, 85% vs 67%; grades 3-4, 30% vs 14%[1]
- Incidence of neutropenia in the NINLARO and Rd regimens,* respectively: any grade, 74% vs 70%; grades 3-4, 34% vs 37%[1]

Safety in high-risk§ patient population

- The overall safety profiles in the high-risk and standard-risk cytogenetics patients in each group are consistent with data reported for the overall population[11]
- As seen in the overall population, in both high-risk and standard-risk cytogenetics patients, common adverse events were primarily of grade 1 or 2 severity and included diarrhea, constipation, neutropenia, and anemia[11]

*The NINLARO regimen included NINLARO + lenalidomide + dexamethasone. The Rd regimen included placebo + lenalidomide + dexamethasone.[1]

†Represents a pooling of preferred terms.[1]

‡At the time of the final analysis, these ARs no longer met the criterion for a ≥5% difference between the NINLARO regimen and the placebo regimen.[1]

§Defined as patients with del(17p), t(4;14), and/or t(14;16).[9]

AR=adverse reaction.

IMPORTANT SAFETY INFORMATION

WARNINGS AND PRECAUTIONS (cont'd)

- **Cutaneous Reactions.** Stevens-Johnson syndrome and toxic epidermal necrolysis, including fatal cases, have been reported with NINLARO. If Stevens-Johnson syndrome or toxic epidermal necrolysis occurs, discontinue NINLARO and manage as clinically indicated. Rash, most commonly maculo-papular and macular rash, was reported with NINLARO. Rash resulted in discontinuation of one or more of the three drugs in <1% of patients in both regimens. Manage rash with supportive care or with dose modification if Grade 2 or higher.

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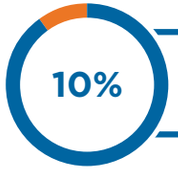
THE NINLARO® (ixazomib) TRIPLET REGIMEN* DEMONSTRATED A SAFETY PROFILE APPROPRIATE FOR LONG-TERM† TREATMENT

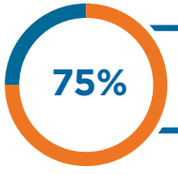
AT FINAL SAFETY ANALYSIS‡[1]

THE MAJORITY OF PATIENTS DID NOT EXPERIENCE PERMANENT DISCONTINUATION OF NINLARO DUE TO ARs[1]



After a median follow-up of ~85 months, permanent discontinuation of NINLARO due to an AR occurred in 10% of patients[1,12]

THE MAJORITY OF PATIENTS CONTINUED AT THE STARTING DOSE OF NINLARO WITHOUT DOSE REDUCTION[12]



of patients (n=269/361) receiving NINLARO + Rd in TOURMALINE-MM1 continued on their starting NINLARO dose§[12]

- The median relative dose intensity for NINLARO + Rd and placebo + Rd was high and similar between both arms: 97.8% and 100%, respectively[12]
- Relative dose intensity was calculated as: 100 x (total amount of dose taken) ÷ (total prescribed dose of treated cycles)¶[12]
- Serious ARs reported in ≥2% of patients in the NINLARO regimen included diarrhea (3%), thrombocytopenia (2%), and bronchitis (2%)[1]

THE NINLARO TRIPLET REGIMEN* MAY OFFER PATIENTS LIKE ALICE EXTENDED EFFICACY WITH SAFETY THAT IS SIMILAR TO A DOUBLET[1,9]

*The NINLARO regimen includes NINLARO + lenalidomide + dexamethasone.[1]
†Treatment to disease progression or unacceptable toxicity.[1]
‡Data cut-off for the final analysis: 28 September 2020.[12]
§Median duration of exposure to NINLARO was 457 days (range: 1–2768 days).[13]
¶Total prescribed dose equals (dose prescribed at enrollment × number of prescribed doses per cycle × the number of treated cycles).[12]
AE=adverse event; AR=adverse reaction; Rd=lenalidomide+dexamethasone.

IMPORTANT SAFETY INFORMATION

WARNINGS AND PRECAUTIONS (cont'd)

- **Thrombotic Microangiopathy** has been reported with NINLARO. Fatal cases of thrombotic microangiopathy, including thrombotic thrombocytopenic purpura/hemolytic uremic syndrome (TTP/HUS), have been reported in patients who received NINLARO. Monitor for signs and symptoms of TTP/HUS. If the diagnosis is suspected, stop NINLARO and evaluate. If the diagnosis of TTP/HUS is excluded, consider restarting NINLARO. The safety of reinitiating NINLARO therapy in patients previously experiencing TTP/HUS is not known.

Please see additional Important Safety Information throughout and NINLARO (ixazomib) full Prescribing Information.

DOSING: CONSIDER AN ALL-ORAL PI-BASED REGIMEN YOUR PATIENTS CAN TAKE AT HOME[1,7,8]

DOSING SCHEDULE[1]

WEEK 1	DAY 1	DAY 2	DAY 3	DAY 4	DAY 5	DAY 6	DAY 7
WEEK 2	DAY 8	DAY 9	DAY 10	DAY 11	DAY 12	DAY 13	DAY 14
WEEK 3	DAY 15	DAY 16	DAY 17	DAY 18	DAY 19	DAY 20	DAY 21
WEEK 4	DAY 22	DAY 23 NO DOSE	DAY 24 NO DOSE	DAY 25 NO DOSE	DAY 26 NO DOSE	DAY 27 NO DOSE	DAY 28 NO DOSE

NINLARO (4 mg, 3 mg, 2.3 mg) Lenalidomide (25 mg) Dexamethasone (40 mg)

As the graphic shows,
NINLARO is administered orally on days 1, 8, and 15 of a 28-day cycle.[1]
Lenalidomide is administered orally on days 1-21 of a 28-day cycle.[1,7]
Dexamethasone is administered orally on days 1, 8, 15, and 22 of a 28-day cycle.[1,8]
Please note that there is **NO DOSING** on days 23-28.

- Advise patients to take NINLARO once a week on the same day and at approximately the same time for the first 3 weeks of a 4-week cycle. The importance of carefully following all dosage instructions should be discussed with patients starting treatment. Instruct patients to take the recommended dosage as directed because overdosage has led to deaths[1]
- The recommended starting dose of NINLARO is 4 mg (one capsule) in combination with lenalidomide and dexamethasone[1]
- A 3-mg starting dose is recommended for patients with moderate or severe hepatic impairment and patients with severe renal impairment or end-stage renal disease requiring dialysis. A 2.3-mg dose is also available for subsequent dose reductions due to ARs[1]

AR=adverse reaction; PI=proteasome inhibitor.

IMPORTANT SAFETY INFORMATION

WARNINGS AND PRECAUTIONS (cont'd)

- **Hepatotoxicity** has been reported with NINLARO. Drug-induced liver injury, hepatocellular injury, hepatic steatosis, hepatitis cholestatic and hepatotoxicity have each been reported in <1% of patients treated with NINLARO. Hepatotoxicity has been reported (10% in the NINLARO regimen and 9% in the placebo regimen). Monitor hepatic enzymes regularly and adjust dosing for Grade 3 or 4 symptoms.

NINLARO® (ixazomib) capsules
4mg | 3mg | 2.3mg

INDICATION AND USAGE

Indication: NINLARO® (ixazomib) is indicated in combination with lenalidomide and dexamethasone for the treatment of patients with multiple myeloma who have received at least one prior therapy.

Limitations of Use: NINLARO is not recommended for use in the maintenance setting or in newly diagnosed multiple myeloma in combination with lenalidomide and dexamethasone outside of controlled clinical trials.

IMPORTANT SAFETY INFORMATION

WARNINGS AND PRECAUTIONS

- **Thrombocytopenia** has been reported with NINLARO. Platelet nadirs typically occurred between Days 14-21 of each 28-day cycle and recovered to baseline by the start of the next cycle. Grade 3 thrombocytopenia was reported in 17% of patients in the NINLARO regimen and Grade 4 thrombocytopenia was reported in 13% in the NINLARO regimen. During treatment, monitor platelet counts at least monthly, and consider more frequent monitoring during the first three cycles. Manage thrombocytopenia with dose modifications and platelet transfusions as per standard medical guidelines.
- **Gastrointestinal Toxicities,** including diarrhea, constipation, nausea and vomiting were reported with NINLARO and may occasionally require the use of antidiarrheal and antiemetic medications, and supportive care. Diarrhea resulted in the discontinuation of one or more of the three drugs in 3% of patients in the NINLARO regimen and 2% of patients in the placebo regimen. Adjust dosing for Grade 3 or 4 symptoms.
- **Peripheral Neuropathy** was reported with NINLARO. The most commonly reported reaction was peripheral sensory neuropathy (24% and 17% in the NINLARO and placebo regimens, respectively). Peripheral motor neuropathy was not commonly reported in either regimen (<1%). Peripheral neuropathy resulted in discontinuation of one or more of the three drugs in 4% of patients in the NINLARO regimen and <1% of patients in the placebo regimen. During treatment, monitor patients for symptoms of neuropathy and consider adjusting dosing for new or worsening peripheral neuropathy.
- **Peripheral Edema** was reported with NINLARO. Evaluate for underlying causes and provide supportive care, as necessary. Adjust dosing of NINLARO for Grade 3 or 4 symptoms or dexamethasone per its prescribing information.
- **Cutaneous Reactions.** Stevens-Johnson syndrome and toxic epidermal necrolysis, including fatal cases, have been reported with NINLARO. If Stevens-Johnson syndrome or toxic epidermal necrolysis occurs, discontinue NINLARO and manage as clinically indicated. Rash, most commonly maculo-papular and macular rash, was reported with NINLARO. Rash resulted in discontinuation of one or more of the three drugs in <1% of patients in both regimens. Manage rash with supportive care or with dose modification if Grade 2 or higher.
- **Thrombotic Microangiopathy** has been reported with NINLARO. Fatal cases of thrombotic microangiopathy, including thrombotic thrombocytopenic purpura/hemolytic uremic syndrome (TTP/HUS), have been reported in patients who received NINLARO. Monitor for signs and symptoms of TTP/HUS. If the diagnosis is suspected, stop NINLARO and evaluate. If the diagnosis of TTP/HUS is excluded, consider restarting NINLARO. The safety of reinitiating NINLARO therapy in patients previously experiencing TTP/HUS is not known.

Please see additional Important Safety Information throughout and NINLARO (ixazomib) full Prescribing Information.

IMPORTANT SAFETY INFORMATION (cont'd)

WARNINGS AND PRECAUTIONS (cont'd)

- **Hepatotoxicity** has been reported with NINLARO. Drug-induced liver injury, hepatocellular injury, hepatic steatosis, hepatitis cholestatic and hepatotoxicity have each been reported in <1% of patients treated with NINLARO. Hepatotoxicity has been reported (10% in the NINLARO regimen and 9% in the placebo regimen). Monitor hepatic enzymes regularly and adjust dosing for Grade 3 or 4 symptoms.
- **Embryo-fetal Toxicity:** NINLARO can cause fetal harm. Advise pregnant women of the potential risk to a fetus. Advise females of reproductive potential to use effective non-hormonal contraception during treatment with NINLARO and for 90 days following the last dose. Advise males with female partners of reproductive potential to use effective contraception during treatment with NINLARO and for 90 days following the last dose.
- **Increased Mortality in Patients Treated with NINLARO in the Maintenance Setting:** In two prospective randomized clinical trials in multiple myeloma in the maintenance setting, treatment with NINLARO resulted in increased deaths. Treatment of patients with NINLARO for multiple myeloma in the maintenance setting is not recommended outside of controlled trials.

ADVERSE REACTIONS

The most common adverse reactions (≥ 20%) in the NINLARO regimen compared to placebo in combination with lenalidomide plus dexamethasone, respectively were thrombocytopenia (85%, 67%; pooled from adverse event and laboratory data), neutropenia (74%, 70%; pooled from adverse event and laboratory data), diarrhea (52%, 43%), constipation (35%, 28%), peripheral neuropathy (32%, 24%), nausea (32%, 23%), edema peripheral (27%, 21%), rash (27%, 16%), vomiting (26%, 13%), and bronchitis (22%, 17%). Serious adverse reactions reported in ≥ 2% of patients in the NINLARO regimen included diarrhea (3%), thrombocytopenia (2%), and bronchitis (2%).

DRUG INTERACTIONS: Avoid concomitant administration of NINLARO with strong CYP3A inducers.

USE IN SPECIFIC POPULATIONS

- **Lactation:** Advise women not to breastfeed during treatment with NINLARO and for 90 days after the last dose.
- **Hepatic Impairment:** Reduce the NINLARO starting dose to 3 mg in patients with moderate or severe hepatic impairment.
- **Renal Impairment:** Reduce the NINLARO starting dose to 3 mg in patients with severe renal impairment or end-stage renal disease requiring dialysis. NINLARO is not dialyzable.

To report SUSPECTED ADVERSE REACTIONS, contact Takeda Pharmaceuticals at 1-844-617-6468 or the FDA at 1-800-FDA-1088 or **www.fda.gov/medwatch**.

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NINLARO®
(ixazomib) capsules
4mg | 3mg | 2.3mg

THE NINLARO® (ixazomib) REGIMEN* OFFERS LONG-TERM† PROTEASOME INHIBITION UNTIL PROGRESSION[1,9]

EFFICACY

In TOURMALINE-MM1, mPFS was extended by ~6 months (20.6 months with the NINLARO triplet regimen* compared with 14.7 months with the Rd regimen*).[1]

TOLERABILITY

- In TOURMALINE-MM1, permanent discontinuation of NINLARO due to an AR occurred in 10% of patients[‡1,12]
- 75% of patients receiving the NINLARO regimen* in TOURMALINE-MM1 continued on their starting dose of NINLARO[§12]
- Serious ARs reported in ≥2% of patients included diarrhea (3%), thrombocytopenia (2%), and bronchitis (2%)[1]

CONVENIENT DOSING

The NINLARO triplet regimen* is the first and only PI-based therapy with the convenience of all-oral administration.[1,7,8]

OFFER THE NINLARO REGIMEN TO YOUR ACTIVE ELDERLY PATIENT AT FIRST RELAPSE

*The NINLARO regimen includes NINLARO + lenalidomide + dexamethasone. The Rd regimen includes lenalidomide + dexamethasone.[1]
†Used herein to refer to treatment to disease progression or unacceptable toxicity.[1]
‡After a median follow-up of ~85 months; data cut-off for the final analysis: 28 September 2020.[12]
§Median duration of exposure to NINLARO was 457 days (range: 1–2768 days).[13]
AR=adverse reaction; mPFS=median progression-free survival; PI=proteasome inhibitor.

IMPORTANT SAFETY INFORMATION

SUMMARY OF WARNINGS AND PRECAUTIONS

- Warnings and Precautions for NINLARO include thrombocytopenia, gastrointestinal toxicities, peripheral neuropathy, peripheral edema, cutaneous reactions including fatal cases of Stevens-Johnson syndrome and toxic epidermal necrolysis, thrombotic microangiopathy including fatal cases, hepatotoxicity, embryo-fetal toxicity, and increased mortality in patients treated with NINLARO in the maintenance setting

ADVERSE REACTIONS

The most common adverse reactions (≥20%) in the NINLARO regimen compared to placebo in combination with lenalidomide plus dexamethasone, respectively were thrombocytopenia (85%, 67%; pooled from adverse event and laboratory data), neutropenia (74%, 70%; pooled from adverse event and laboratory data), diarrhea (52%, 43%), constipation (35%, 28%), peripheral neuropathy (32%, 24%), nausea (32%, 23%), edema peripheral (27%, 21%), rash (27%, 16%), vomiting (26%, 13%), and bronchitis (22%, 17%). Serious adverse reactions reported in ≥2% of patients in the NINLARO regimen included diarrhea (3%), thrombocytopenia (2%), and bronchitis (2%).

To report SUSPECTED ADVERSE REACTIONS, contact Takeda Pharmaceuticals at 1-844-617-6468 or the FDA at 1-800-FDA-1088 or **www.fda.gov/medwatch**.

Please see additional Important Safety Information throughout and NINLARO (ixazomib) full Prescribing Information.

References: 1. NINLARO. Prescribing information. Takeda Pharmaceuticals America, Inc.; 03/2024. **2.** Data on File. Takeda Pharmaceuticals U.S.A., Inc.; 2022. **3.** Borrello I. Can we change the disease biology of multiple myeloma? *Leuk Res.* 2012;36 Suppl 1(0 1):S3-S12. **4.** Sonneveld P. Management of multiple myeloma in the relapsed/refractory patient. *Hematology Am Soc Hematol Educ Program.* 2017;2017(1):508-517. **5.** Durie BGM. *Concise Review of the Disease and Treatment Options: Multiple Myeloma: Cancer of the Bone Marrow.* 2011/2012 ed. International Myeloma Foundation; 2011. **6.** Mina R, Bringhen S, Wildes TM, et al. Approach to the older adult with multiple myeloma. *Am Soc Clin Oncol Educ Book.* 2019;39:500-518. **7.** Revlimid. Prescribing information. Celgene Corporation; 03/2023. **8.** Hemady. Prescribing information. Acrotech Biopharma LLC; 06/2021. **9.** Moreau P, Masszi T, Grzasko N, et al; for TOURMALINE-MM1 Study Group. Oral ixazomib, lenalidomide, and dexamethasone for multiple myeloma. *N Engl J Med.* 2016;374(17):1621-1634. **10.** Moreau P, Masszi T, Grzasko N, et al; for TOURMALINE-MM1 Study Group. Oral ixazomib, lenalidomide, and dexamethasone for multiple myeloma. *N Engl J Med.* 2016;374(17):1621-1634 [supplemental appendix]. **11.** Avet-Loiseau H, Bahlis NJ, Chng W-J, et al. Ixazomib significantly prolongs progression-free survival in high-risk relapsed/refractory myeloma patients. *Blood.* 2017;130(24):2610-2618. **12.** Data on File. Takeda Pharmaceuticals U.S.A., Inc.; 2023. **13.** Data on File. Takeda Pharmaceuticals U.S.A., Inc.; 2024.

NINLARO® (ixazomib) capsules
4mg | 3mg | 2.3mg