

You are invited!

NINLARO® (ixazomib): An Oral Treatment Option

Presented by

Edgardo S. Santos, MD

Medical Doctor of Cancer Research
Lynn Cancer Institute

Friday, July 22, 2016

12:30 PM

The Roosevelt Hotel
130 Roosevelt Way, Chamber Rooms, New Orleans, LA 70119
(504) 648-1200

Hosted by

Kenny Otilio

Senior Oncology Specialist
Takeda

**RSVP via e-mail to epic@theselvagroup.com
or fax to 800-660-8857 before 07/20/2016.**

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.

Full Name	Credentials	Title		
Institution		City	State	ZIP Code
Email Address		Phone	E11380	
License Number (only if licensed in MA or MN)		Meeting Code		

Sponsored by Takeda. Please note that this is not a continuing medical education (CME) program.

IMPORTANT SAFETY INFORMATION

WARNINGS AND PRECAUTIONS

- **Thrombocytopenia** has been reported with NINLARO. 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. Adjust dosing as needed. Platelet nadirs occurred between Days 14-21 of each 28-day cycle and recovered to baseline by the start of the next cycle.

**Please see additional Important Safety Information continued on page 2
and accompanying NINLARO full Prescribing Information.**

Important Safety Information for NINLARO® (ixazomib) (continued)

WARNINGS AND PRECAUTIONS (continued)

- **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 1% of patients in the NINLARO regimen and < 1% of patients in the placebo regimen. Adjust dosing for severe symptoms.
- **Peripheral Neuropathy** (predominantly sensory) was reported with NINLARO. The most commonly reported reaction was peripheral sensory neuropathy (19% and 14% 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 1% of patients in both regimens. Monitor patients for symptoms of peripheral neuropathy and adjust dosing as needed.
- **Peripheral Edema** was reported with NINLARO. Monitor for fluid retention. Investigate for underlying causes when appropriate and provide supportive care as necessary. Adjust dosing of dexamethasone per its prescribing information or NINLARO for Grade 3 or 4 symptoms.
- **Cutaneous Reactions**: 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.
- **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. Events of liver impairment have been reported (6% in the NINLARO regimen and 5% in the placebo regimen). Monitor hepatic enzymes regularly during treatment and adjust dosing as needed.
- **Embryo-fetal Toxicity**: NINLARO can cause fetal harm. Women should be advised of the potential risk to a fetus, to avoid becoming pregnant, and to use contraception during treatment and for an additional 90 days after the final dose of NINLARO.

ADVERSE REACTIONS

The most common adverse reactions ($\geq 20\%$) in the NINLARO regimen and greater than the placebo regimen, respectively, were diarrhea (42%, 36%), constipation (34%, 25%), thrombocytopenia (78%, 54%; pooled from adverse events and laboratory data), peripheral neuropathy (28%, 21%), nausea (26%, 21%), peripheral edema (25%, 18%), vomiting (22%, 11%), and back pain (21%, 16%). Serious adverse reactions reported in $\geq 2\%$ of patients included thrombocytopenia (2%) and diarrhea (2%).

SPECIAL POPULATIONS


- **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.
- **Lactation**: Advise women to discontinue nursing while on NINLARO.

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

Please see accompanying NINLARO full Prescribing Information.



ONCOLOGY

Takeda Oncology and  are registered trademarks of Takeda Pharmaceutical Company Limited. NINLARO is a registered trademark of Millennium Pharmaceuticals, Inc.

Copyright © 2016, Millennium Pharmaceuticals, Inc.
All rights reserved.

4/16

USO/IXA/15/0070(2)

 **NINLARO**[®]
(ixazomib) capsules
4mg | 3mg | 2.3mg