global myeloma action network
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New Format for GMAN Newsletter Coming Soon

Next month, changes will occur to the GMAN newsletter that will make it more accessible for our members. The format will be altered and new sections will be added that readers should find interesting and useful. We sincerely hope that everyone will enjoy the new design and we are open to feedback about the new look. Until then, enjoy the "vintage" version of our GMAN newsletter.

Ninlaro Approved for Canada

Takeda Pharmaceutical announced on August 8th that Takeda Canada has received approval from Health Canada for Ninlaro (ixazomib) capsules in combination with lenalidomide and dexamethasone for the treatment of adult patients with multiple myeloma who have received at least one prior therapy. In Canada, it is estimated that approximately 7,500 people live with multiple myeloma. The approval was primarily based on the results of the final analysis of the pivotal Phase 3 trial, TOURMALINE-MM1, which demonstrated that Ninlaro in combination with lenalidomide and dexamethasone significantly extended progression-free survival, with a manageable safety profile in patients with relapsed/ refractory multiple myeloma. Due to the high unmet need in multiple myeloma, the New Drug Submission for Ninlaro was granted a Priority Review by Health Canada.

NINLARO® (ixazomib) capsules

Marketing applications for NINLARO are currently under review by several regulatory authorities around the world. To read more about Canada's approval of Ninlaro, please click here.

Expanded Indication Sought for Daratumumab in US

Janssen Biotech, Inc. announced on August 17 a supplemental Biologics License Application (sBLA) for daratumumab (Darzalex) has been submitted to the U.S. Food and Drug Admin-is-tra-tion (FDA). The application seeks to expand the current indication, using daratumumab in combination with lenalidomide (an immunomodulatory agent) and dexamethasone, or bortezomib (a proteasome inhibitor [PI]) and dexamethasone, for the treatment of patients with multiple myeloma who have received at least one prior therapy. Daratumumab received Breakthrough Therapy Designation from the FDA for this pending indication on July 25, 2016.

DARZALEX™ (daratumumab) injection for intravenous infusion 100 mg/5 mL, 400 mg/20 mL

"Daratumumab has been shown to provide clinically meaningful benefit as a backbone therapy in combi-na-tion with two of the most widely used treatment regimens for multiple myeloma," said Peter F. Lebowitz, M.D., Ph.D., Global Oncology Head, Janssen Research & Development, LLC. "Today's submission marks an important step forward in realizing the full potential of daratumumab earlier in the treatment pathway, and we look forward to working with the FDA during its review of our application."

Janssen has also submitted a request for Priority Review of this sBLA. The FDA will inform Janssen whether a Priority Review has been granted within the next 60 days. If the FDA grants Priority Review, the review should be completed within six months from August 17th. To read the full press release, click here.

To submit a news story for publication, please contact Raymond Wezik, Global Advocacy Executive, International Myeloma Foundation at rwezik@myeloma.org.