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J&J's DARZALEX gets USFDA approval to treat multiple myeloma

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Combination regimen reduced the risk of disease progression or death by 44 percent in newly diagnosed patients who are transplant ineligible

The Janssen Pharmaceutical Companies of Johnson & Johnson has announced the U.S. Food and Drug Administration (FDA) approval of DARZALEX® (daratumumab) in combination with lenalidomide and dexamethasone (Rd) for the treatment of patients with newly diagnosed multiple myeloma who are ineligible for autologous stem cell transplant (ASCT). The approval is based on results from the Phase 3 MAIA (MMY3008) clinical study, which showed that DARZALEX-Rd significantly reduced the risk of disease progression or death by 44 percent compared to treatment with Rd alone.The application received approval through the U.S. FDA's Real-Time Oncology Review (RTOR) pilot program.

"Multiple myeloma can become more difficult to treat after relapse, so it is important that patients receive an efficacious upfront therapy with a goal of extending their first remission period," said Saad Usmani, M.D., FACP, Department of Hematologic Oncology and Blood Disorders, Levine Cancer Institute/Carolinas HealthCare System, and a lead investigator of the MAIA study. "This daratumumab regimen offers an important frontline treatment option for this patient population, and it has been submitted to the NCCN Multiple Myeloma Panel for review and consideration for potential inclusion in the NCCN Clinical Practice Guidelines."

"For patients with multiple myeloma, optimizing response to frontline treatment is critical," said Paul Giusti, President and CEO of the Multiple Myeloma Research Foundation. "This latest indication for DARZALEX is a promising development for the myeloma community, and we are grateful to Janssen, our long-standing partner in myeloma research, as well as the patients with myeloma and healthcare providers involved in this study."

"Today's approval of DARZALEX underscores the significant clinical benefit of this CD38 monoclonal antibody and our efforts to advance treatment paradigms to change the course of the disease," said Craig Tendler, M.D., Vice President, Clinical Development and Global Medical Affairs, Oncology, Janssen Research & Development, LLC. "Importantly, this milestone also highlights the efficiency of the FDA's Real-Time Oncology Review process, ensuring that proven treatment regimens, such as DARZALEX plus lenalidomide and dexamethasone, are made available to patients as soon as possible."