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Janssen submits application to get USFDA nod for DARZALEX

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Submission inclusive of data from Phase 3 COLUMBA study presented at ASCO



The Janssen Pharmaceutical Companies of Johnson & Johnson has announced the submission of a Biologics License Application (BLA) to the U.S. Food and Drug Administration (FDA) seeking approval of a new subcutaneous (SC) formulation of DARZALEX® (daratumumab), an intravenous (IV) treatment approved for certain patients with multiple myeloma.

The submission is supported by data from the Phase 3 COLUMBA (MMY3012) study first presented at the American Society of Clinical Oncology (ASCO) Annual Meeting that included a non-inferiority comparison to DARZALEX IV administration for co-primary endpoints of overall response rate and maximum C_{trough} concentration. Data from the Phase 2 PLEIADES (MMY2040) study are also included in the BLA. The subcutaneous formulation of DARZALEX is co-formulated with recombinant human hyaluronidase PH20 (rHuPH20) [Halozyme's *ENHANZE*® drug delivery technology].

"This submission represents our commitment to develop innovative treatment options for people living with multiple myeloma," said Craig Tendler, M.D., Vice President, Clinical Development and Global Medical Affairs, Oncology, Janssen Research & Development, LLC. "The DARZALEX subcutaneous formulation showed non-inferiority to the existing IV formulation, both as a monotherapy and in combination with common background therapies, while administered with a considerably shorter infusion time. We look forward to working closely with the FDA in their review of the data supporting this regulatory application."

Today's submission follows two recent milestones for the DARZALEX intravenous formulation, including an approval of DARZALEX in combination with lenalidomide and dexamethasone for the treatment of newly diagnosed, transplant ineligible patients with multiple myeloma supported by the Phase 3 MAIA study, and Priority Review designation following submission of a supplemental BLA based on the Phase 3 CASSIOPEIA study, which is seeking approval of DARZALEX in combination with bortezomib, thalidomide and dexamethasone for newly diagnosed patients with multiple myeloma who are transplant eligible.