Darzalex® (daratumumab) – Expanded indication

- On June 27, 2019, Janssen announced the FDA approval of Darzalex (daratumumab), in combination with Revlimid® (lenalidomide) and dexamethasone, for the treatment of newly diagnosed multiple myeloma patients who are ineligible for autologous stem cell transplant.

- Darzalex is also approved for the treatment of adult patients with multiple myeloma:

    - In combination with Revlimid and dexamethasone in patients with relapsed or refractory multiple myeloma who have received at least one prior therapy
    - In combination with Velcade® (bortezomib), melphalan and prednisone in newly diagnosed patients who are ineligible for autologous stem cell transplant
    - In combination with Velcade and dexamethasone in patients who have received at least one prior therapy
    - In combination with Pomalyst® (pomalidomide) and dexamethasone in patients who have received at least two prior therapies including Revlimid and a proteasome inhibitor
    - As monotherapy, in patients who have received at least three prior lines of therapy including a proteasome inhibitor (PI) and an immunomodulatory agent or who are double-refractory to a PI and an immunomodulatory agent.

- Multiple myeloma is an incurable blood cancer that affects a type of white blood cell called plasma cells. When damaged, these plasma cells rapidly spread and replace normal cells with tumors in the bone marrow. In 2019, it is estimated that more than 32,000 people will be diagnosed, and nearly 13,000 will die from the disease, in the U.S.

- The approval of Darzalex for this expanded indication was based on an open-label study in 737 patients with newly diagnosed multiple myeloma ineligible for autologous stem cell transplant. Patients were randomized to receive Darzalex + Revlimid + dexamethasone or Revlimid + dexamethasone alone. Efficacy was evaluated by progression free survival (PFS).

    - The median PFS had not been reached in the Darzalex + Revlimid + dexamethasone arm and was 31.9 months in the Revlimid + dexamethasone arm (hazard ratio: 0.56; 95% CI: 0.43, 0.73; $p < 0.0001$), representing a 44% reduction in the risk of disease progression or death in patients treated with Darzalex + Revlimid + dexamethasone.
    - The overall response rate was 92.9% in the Darzalex + Revlimid + dexamethasone arm vs. 81.3% in the Revlimid + dexamethasone arm ($p < 0.0001$).
    - The median duration of response had not been reached in the Darzalex + Revlimid + dexamethasone group and was 34.7 months (95% CI: 30.8, not estimable) in the Revlimid + dexamethasone group.

- The recommended dosage of Darzalex for all indications is 16 mg/kg actual body weight administered as an intravenous infusion.

    - Pre-infusion and post-infusion medications should be administered.
    - Darzalex should be administered by a healthcare professional, with immediate access to emergency equipment and appropriate medical support to manage infusion reactions if they occur.
    - Consult the Darzalex drug label for the recommended dosing schedule of Darzalex for all indications.

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— Consult individual drug labels for dosing recommendations for drugs used in combination with Darzalex.

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