Darzalex® (daratumumab) – Expanded indication

- On May 7, 2018, Janssen announced the FDA approval of Darzalex (daratumumab), in combination with Velcade® (bortezomib), melphalan, and prednisone (VMP) for the treatment of patients with newly diagnosed multiple myeloma (MM) who are ineligible for autologous stem cell transplant.

- Darzalex is also approved to treat the following:

    - In combination with Revlimid® (lenalidomide) and dexamethasone, or Velcade and dexamethasone, for the treatment of patients with MM who have received at least one prior therapy
    - In combination with Pomalyst® (pomalidomide) and dexamethasone for the treatment of patients with MM who have received at least two prior therapies including Revlimid and a proteasome inhibitor (PI)
    - As monotherapy, for the treatment of patients with MM who have received at least three prior lines of therapy including a PI and an immunomodulatory agent or who are double-refractory to a PI and an immunomodulatory agent.

- MM is an incurable blood cancer that occurs when malignant plasma cells grow uncontrollably in the bone marrow. Symptoms include bone fracture or pain, low red blood counts, fatigue, calcium elevation, kidney problems or infections.

    - According to the American Cancer Society, there will be about 30,770 new cases of MM diagnosed and about 12,770 deaths are expected to occur in the U.S. in 2018.

- The approval of Darzalex for the expanded indication was based on the ALCYONE study. A total of 706 patients with newly diagnosed MM who were ineligible for stem-cell transplantation were randomized to VMP either alone or with Darzalex until disease progression. The primary end point was progression-free survival (PFS).

    - At a median follow-up of 16.5 months in a prespecified interim analysis, the 18-month PFS rate was 71.6% (95% CI: 65.5, 76.8) in the Darzalex group and 50.2% (95% CI: 43.2, 56.7) in the control group (hazard ratio for disease progression or death: 0.50 [95% CI: 0.38, 0.65; $p < 0.001$]).

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