Darzalex® (daratumumab) – Expanded indication

- On June 16, 2017, Janssen announced the FDA approval of Darzalex (daratumumab), in combination with Pomalyst® (pomalidomide) and dexamethasone for the treatment of patients with multiple myeloma who have received at least two prior therapies including Revlimid® (lenalidomide) and a proteasome inhibitor (PI).

- Darzalex is also indicated in combination with lenalidomide and dexamethasone, or Velcade® (bortezomib) and dexamethasone, for the treatment of patients with multiple myeloma who have received at least one prior therapy and as monotherapy, for the treatment of patients with multiple myeloma 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.

- The expanded indication for Darzalex was approved based on the open-label EQUULEUS study that enrolled 103 patients with multiple myeloma who had received a prior PI and an immunomodulatory agent. Patients received Darzalex in combination with Pomalyst and low-dose dexamethasone until disease progression. Efficacy results were based on overall response rate (ORR).

    - The ORR was 59.2% (95% CI: 49.1, 68.8).
    - The median time to response was 1 month (range: 0.9 to 2.8 months).
    - The median duration of response was 13.6 months (range: 0.9+ to 14.6+ months).

- The recommended dose of Darzalex for all indications is 16 mg/kg actual body weight administered as an intravenous infusion in a dosing schedule outlined in the drug label.

- Consult individual drug labels for recommended dosages of combination agents.