Darzalex Faspro® (daratumumab and hyaluronidase-fihj) – Expanded indication

- On July 12, 2021, Janssen announced the FDA approval of Darzalex Faspro (daratumumab and hyaluronidase-fihj), in combination with Pomalyst® (pomalidomide) and dexamethasone, for the treatment of adult patients with multiple myeloma in patients who have received at least one prior line of therapy including Revlimid® (lenalidomide) and a proteasome inhibitor.

- Darzalex Faspro is also approved for various other uses in multiple myeloma. Refer to the drug label for additional information.

- The approval of Darzalex Faspro for the expanded indication was based on APOLLO, an open label, randomized, active-controlled study in 304 patients with multiple myeloma. Patients received Darzalex Faspro plus Pomalyst and dexamethasone or Pomalyst and dexamethasone alone. The major efficacy outcome measure was progression-free survival (PFS).

    — The median PFS was 12.4 months in the Darzalex Faspro combination group vs. 6.9 months in the Pomalyst plus dexamethasone group (hazard ratio 0.63, 95% CI: 0.47, 0.85; p = 0.0018).
    — Overall response was 68.9% in the Darzalex Faspro combination group vs. 46.4% in the Pomalyst plus dexamethasone group (p < 0.0001).

- The recommended dose of Darzalex Faspro is 1,800 mg/30,000 units (1,800 mg daratumumab and 30,000 units hyaluronidase) administered subcutaneously over approximately 3 to 5 minutes. When used in combination with Pomalyst and dexamethasone, the recommend dosing schedule is weekly for weeks 1 to 8, every two weeks for weeks 9 to 24, and every four weeks for weeks 25 onwards until disease progression.

    — Darzalex Faspro should be administered by a healthcare provider.
    — Refer to the drug labels for Pomalyst and dexamethasone for their dosage recommendations.
    — Refer to the Darzalex Faspro drug label for dosing for all its other uses.