Darzalex Faspro® (daratumumab/hyaluronidase-fihj), Kyprolis® (carfilzomib) – Expanded indication

- On December 1, 2021, the FDA approved Janssen's Darzalex Faspro (daratumumab/hyaluronidase-fihj) and Amgen's Kyprolis (carfilzomib), in combination with dexamethasone, for the treatment of adult patients with relapsed or refractory multiple myeloma who have received one to three prior lines of therapy.

- Darzalex Faspro and Kyprolis were each previously approved for various other uses in multiple myeloma. Additionally, Darzalex Faspro is also approved for newly diagnosed light chain amyloidosis.

- The approval of Darzalex Faspro and Kyprolis' expanded indication was based on a single-arm cohort of PLEIADES, an open-label study in 66 patients with relapsed or refractory multiple myeloma. Patients received Darzalex Faspro, Kyprolis, and dexamethasone until disease progression or unacceptable toxicity. The major efficacy outcome measure was overall response rate (ORR).

    - The ORR was 84.8% (95% CI: 73.9, 92.5).
    - At a median follow-up of 9.2 months, the median duration of response had not been reached.

- 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 Kyprolis and dexamethasone, Darzalex Faspro should be administered weekly during weeks 1 to 8, every two weeks during weeks 9 to 24, and every four weeks from week 25 onwards until disease progression.

    - Refer to the Darzalex Faspro drug label for dosing and administration recommendations for its other uses.

- When used in combination with Darzalex Faspro and dexamethasone, Kyprolis is administered intravenously and has two separate dosing regimens (twice weekly or once weekly regimen).

    - For the twice weekly regimen, the recommended starting dose of Kyprolis is 20 mg/m^2 on cycle 1, days 1 and 2. If tolerated, the dose is escalated to 56 mg/m^2 on cycle 1, day 8 and thereafter. Kyprolis is administered as a 30-minute infusion on days 1, 2, 8, 9, 15 and 16 of each 28-day cycle until disease progression or unacceptable toxicity.
    - For the once weekly regimen, the recommended starting dose of Kyprolis is 20 mg/m^2 on cycle 1, day 1. If tolerated, the dose is escalated to 70 mg/m^2 on cycle 1, day 8 and thereafter. Kyprolis is administered on days 1, 8 and 15 of each 28-day cycle until disease progression or unacceptable toxicity.
    - Refer to the Kyprolis drug label for dosing and administration recommendations for its other uses.