Kyprolis® (carfilzomib) – Expanded indication

- On June 30, 2022, the FDA approved Amgen's Kyprolis (carfilzomib), in combination with Sarclisa® (isatuximab-irfc) and dexamethasone, for the treatment of adult patients with relapsed or refractory multiple myeloma who have received one to three lines of therapy.
    - Kyprolis is also approved for this indication in combination with Revlimid® (lenalidomide) and dexamethasone; or dexamethasone; or Darzalex® (daratumumab) and dexamethasone; or Darzalex Faspro® (daratumumab/hyaluronidase-fihj) and dexamethasone.
- Additionally, Kyprolis is approved as a single agent for the treatment of adult patients with relapsed or refractory multiple myeloma who have received one or more lines of therapy.
- The approval of Kyprolis for the expanded indication was based on IKEMA, a randomized, open-label study in 302 patients with relapsed and/or refractory multiple myeloma. Patients received either Kyprolis in combination with Sarclisa and dexamethasone (Isa-Kd) or Kyprolis and dexamethasone (Kd). Efficacy was based on progression-free survival (PFS).
    - Median PFS was not reached with Isa-Kd vs. 20.27 months with Kd (hazard ratio 0.548, 95% CI: 0.366, 0.822; p = 0.0032).
    - The overall response rate was 86.6% (95% CI: 80.7, 91.2) with Isa-Kd vs. 82.9 (95% CI: 75.1, 89.1) with Kd (p = 0.3859).
- When administered with Sarclisa and dexamethasone, the recommended starting dosage of Kyprolis is 20 mg/m^2 on cycle 1, days 1 and 2. If tolerated, the dose should be escalated to 56 mg/m^2 on cycle 1, day 8. Kyprolis is administered intravenously 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.
    - Refer to the drug label for complete dosing for this use and Kyprolis' other uses.