Kineret® (anakinra) – New indication

- On December 18, 2020, the FDA approved Swedish Orphan Biovitrum's Kineret (anakinra), for the treatment of Deficiency of Interleukin-1 Receptor Antagonist (DIRA).

- Kineret is also approved for active rheumatoid arthritis and Cryopyrin-Associated Periodic Syndromes (CAPS).

- The approval of Kineret for the new indication was based on a long-term natural history study including 9 DIRA patients (ages 1 month to 9 years at the start of Kineret treatment) treated with Kineret for up to 10 years. Inflammatory remission was defined as achievement of all of the following criteria: C-reactive protein (CRP) ≤ 5 mg/L, no pustulosis, no inflammatory bone disease, and no concomitant glucocorticosteroid use.

    — All 9 patients achieved inflammatory remission while on Kineret treatment.

- The most common adverse reactions with Kineret use for treatment of DIRA were upper respiratory tract infections, rash, pyrexia, influenza like illness, and gastroenteritis.

- The recommended starting dose of Kineret is 1 to 2 mg/kg subcutaneously daily for patients with DIRA. The dose can be individually adjusted to a maximum of 8 mg/kg daily to control active inflammation. Doses should be adjusted in 0.5 to 1 mg/kg increments.

    — Instructions on appropriate use of Kineret should be given by the healthcare provider to the patient or caregiver. Patients or caregivers should not be allowed to administer Kineret until the patient or caregiver has demonstrated a thorough understanding of procedures and an ability to inject the product correctly.
    — Refer to the Kineret drug label for dosing for its other indications.

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