Kineret® (anakinra) – Emergency use authorization granted

- On November 8, 2022, the FDA issued an emergency use authorization (EUA) for Swedish Orphan Biovitrum AB's (Sobi) Kineret (anakinra), for the treatment of coronavirus disease 2019 (COVID-19) in hospitalized adults with positive results of direct SARS-CoV-2 viral testing with pneumonia requiring supplemental oxygen (low- or high-flow oxygen) who are at risk of progressing to severe respiratory failure and likely to have an elevated plasma soluble urokinase plasminogen activator receptor.
    - Kineret is FDA-approved for the treatment of moderately to severely active rheumatoid arthritis, in patients 18 years of age or older; neonatal-onset multisystem inflammatory disease; and deficiency of interleukin-1 receptor antagonist.
- Kineret is an IL-1 receptor antagonist that blocks the IL-1 signaling pathway, which is involved in inflammatory diseases and thought to contribute to inflammation and worsening of COVID-19.
- The efficacy of Kineret for the treatment of 594 hospitalized adult patients with COVID-19 pneumonia who were at risk of developing severe respiratory failure was demonstrated in a randomized, double-blind, placebo-controlled study (SAVE-MORE). Patients received Kineret plus standard of care (SOC) or placebo plus SOC. The primary endpoint of the study was the 11-point WHO Clinical Progression ordinal Scale (CPS) which was compared between the two arms of treatment by day 28. The 11-point WHO-CPS provides a measure of illness severity across a range from 0 (not infected), 1-3 (mild disease), 4-5 (hospitalized – moderate disease), 6-9 (hospitalized – severe disease) to 10 (dead).
    - Patients treated with Kineret had lower odds of more severe disease according to the WHO-CPS at day 28 vs. placebo (odds ratio: 0.37; 95% CI: 0.26, 0.50).
    - By day 28, there were 13 deaths (6.9%) in the placebo arm and 13 deaths (3.2%) in the Kineret arm (hazard ratio: 0.48; 95% CI: 0.22, 1.04; risk difference: -3.7%; 95% CI: -7.7, 0.3).
- Warnings and precautions for Kineret include serious infections, use with tumor necrosis factor blocking agents, hypersensitivity reactions, immunosuppression, immunizations, and neutropenia.
- The most common adverse reaction (≥ 1%) with Kineret use were increased transaminases, neutropenia, rash, and injection site reactions.
- The recommended dose of Kineret under the EUA in adults 18 years of age and older is 100 mg administered daily by subcutaneous injection for 10 days.
    - Refer to the Kineret drug label for dosing for all its FDA-approved indications.

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