Kevzara® (sarilumab) – New indication

- On February 28, 2023, Regeneron and Sanofi announced the FDA approval of Kevzara (sarilumab), for treatment of adult patients with polymyalgia rheumatica who have had an inadequate response to corticosteroids or who cannot tolerate corticosteroid taper.

- Kevzara is also approved for the treatment of adult patients with moderately to severely active rheumatoid arthritis (RA) who have had an inadequate response or intolerance to one or more disease-modifying antirheumatic drugs (DMARDs).

- Kevzara is the first FDA approved treatment for polymyalgia rheumatica.

    — Polymyalgia rheumatica often initially presents with pain and stiffness around the neck, shoulder and hip area and symptoms include fatigue, low-grade fever, and weight loss.

- The approval of Kevzara for the new indication was based on a randomized, double-blind, placebo-controlled study in adults with polymyalgia rheumatica. Patients with active polymyalgia rheumatica were randomized to receive Kevzara every two weeks with a pre-defined 14-week taper of prednisone or placebo every two weeks with a pre-defined 52-week taper of prednisone. Patients experiencing a disease flare or unable to adhere to the assigned prednisone tapering schedule could receive corticosteroids as rescue therapy. The primary endpoint was the proportion of patients with sustained remission at week 52. An additional endpoint was total cumulative corticosteroid dose over 52 weeks.

    — Sustained remission was achieved in 28.3% of patients with Kevzara vs. 10.3% with placebo (treatment difference 18.0, 95% CI: 4.2, 31.8; p = 0.0193).
    — The total actual cumulative prednisone equivalent corticosteroid dose was lower in the Kevzara arm (mean [standard deviation] 1039.5 [612.2] mg and median 777 mg) relative to the placebo arm (mean [standard deviation] 2235.8 [839.4] mg and median 2044 mg).

- Kevzara carries a boxed warning for risk of serious infection.

- The most common adverse reactions (≥ 5%) with Kevzara use for polymyalgia rheumatica were neutropenia, leukopenia and injection site pruritus.

- The recommended dosage of Kevzara is 200 mg once every two weeks given as a subcutaneous injection, in combination with a tapering course of systemic corticosteroids.

    — Kevzara can be used as monotherapy following discontinuation of corticosteroids.
    — Kevzara should be discontinued if the patient develops neutropenia, thrombocytopenia, or liver enzyme abnormalities.
    — Refer to the Kevzara drug label for dosing for RA.