Saphnelo® (anifrolumab-fnia) – New drug approval

- On August 2, 2021, AstraZeneca announced the FDA approval of Saphnelo (anifrolumab-fnia), for the treatment of adult patients with moderate to severe systemic lupus erythematosus (SLE), who are receiving standard therapy.
    - The efficacy of Saphnelo has not been evaluated in patients with severe active lupus nephritis or severe active central nervous system lupus. Use of Saphnelo is not recommended in these situations.
- SLE is an autoimmune disease in which the immune system attacks healthy tissue in the body. People often experience debilitating symptoms, long-term organ damage and poor health-related quality of life.
    - SLE affects up to 300,000 people in the U.S.
- Saphnelo is a fully human monoclonal antibody that binds to subunit 1 of the type I interferon (IFN) receptor, blocking the activity of type I IFNs. Type I IFNs play a role in the pathogenesis of SLE. Approximately 60-80% of adult patients with active SLE express elevated levels of type I IFN inducible genes.
- The safety and efficacy of Saphnelo were evaluated in three 52-week treatment period, multicenter, randomized, double-blind, placebo-controlled studies. All patients had moderate to severe disease despite receiving standard therapy. Efficacy of Saphnelo was established based on assessment of clinical response using the composite endpoints, the British Isles Lupus Assessment Group based Composite Lupus Assessment (BICLA) and the SLE Responder Index (SRI-4).
    - Trial 1 randomized 305 patients. The primary endpoint was a combined assessment of the SRI-4 and the sustained reduction in oral corticosteroids (OCS). SRI-4 response was 62.8% in the Saphnelo treated patients vs. 38.8% in placebo patients (treatment difference: 24.0; 95% CI: 10.9, 37.2). Consistent trends in favor of Saphnelo vs. placebo, on effect of reduction of OCS use, were observed, but the difference was not statistically significant.
    - Trial 2 randomized 457 patients. The primary endpoint was improvement in disease activity evaluated at 52 weeks, measured by SRI-4. SRI-4 response was 49% in the Saphnelo treated patients vs. 43% in placebo patients (treatment difference: 6.0; 95% CI: -4.2, 16.2). This was not a statistically significant improvement.
    - Trial 3 randomized 362 patients. The primary endpoints was improvement in disease activity evaluated at 52 weeks, measured by BICLA. BICLA response was 47.8% in the Saphnelo treated patients vs. 31.5% in the placebo patients (treatment difference: 16.3; 95% CI: 6.3, 26.3; p = 0.001).
- Warnings and precautions for Saphnelo include serious infections; hypersensitivity reactions including anaphylaxis; malignancy, immunization; and not recommended for concomitant use with other biologics.
- The most common adverse reactions (≥ 5%) with Saphnelo use were nasopharyngitis, upper respiratory tract infections, bronchitis, infusion related reactions, herpes zoster and cough.
- The recommended dose of Saphnelo is 300 mg, administered as an intravenous infusion over a 30-minute period, every 4 weeks.

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- AstraZeneca's launch plans for Saphnelo are pending. Saphnelo will be available as a 300 mg/2 mL solution in a single-dose vial.

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