Brand Name: Saphnelo
Generic: anifrolumab-fnia
Type: monoclonal antibody
Year Accepted/Phase: 2021

Mechanism:

Anifrolumab is an interferon receptor antagonist that targets the type I interferon receptor, inhibiting the activity of type I interferon, which is believed to play a central role in the pathogenesis of SLE.

Chemical Structure: N/A

Indication:

Saphnelo is indicated for the treatment of adult patients with moderate to severe systemic lupus erythematosus who are receiving standard therapy.

Clinical trials:

MUSE Trial (Phase IIb)
Pubmed: https://pubmed.ncbi.nlm.nih.gov/31851795/
Purpose: Evaluate the efficacy and safety of anifrolumab in patients with moderate to severe SLE.
Dates: Conducted from 2011 to 2014.
Results: The MUSE trial demonstrated that anifrolumab significantly improved disease activity compared to placebo. Patients receiving anifrolumab had higher rates of disease control and reductions in flares.
Impact: The positive results from this trial provided the basis for proceeding to larger Phase III trials.

TULIP-1 Trial (Phase III)
Pubmed: https://pubmed.ncbi.nlm.nih.gov/36369793/
Purpose: Assess the efficacy and safety of anifrolumab in patients with moderate to severe SLE.
Dates: Conducted from 2015 to 2018.
Results: The TULIP-1 trial showed that anifrolumab did not meet its primary endpoint of a significant reduction in disease activity compared to placebo. However, it demonstrated improvements in secondary endpoints, including reductions in disease flares and improvements in skin disease.
Impact: While the primary endpoint was not met, the trial provided important data on the potential benefits of anifrolumab and informed the design of the subsequent TULIP-2 trial.

TULIP-2 Trial (Phase III)
Purpose: Confirm the efficacy and safety of anifrolumab in patients with moderate to severe SLE.
Dates: Conducted from 2015 to 2019.
Results: The TULIP-2 trial met its primary endpoint, demonstrating that anifrolumab significantly reduced disease activity compared to placebo. Patients treated with anifrolumab showed improved disease control, reduced flares, and better overall outcomes.
Impact: The successful results of the TULIP-2 trial led to the FDA approval of anifrolumab for the treatment of moderate to severe SLE.