Sierra Rheumatology Inc.
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INFORMED CONSENT FOR TREATMENT WITH SAPHNELO (Anifrolumab-fnia)

Saphnelo is a type I interferon (IFN) receptor antagonist, that has been approved by the Food and Drug Administration (FDA) for the treatment of adult patients with moderate to severe systemic lupus erythematosus (SLE). Saphnelo is not indicated for severe active lupus nephritis or severe active CNS lupus.

Mechanism of action - Saphnelo is a human monoclonal antibody that binds to type I interferon (IFN). This binding inhibits type I IFN signaling, thereby blocking the biologic activity of these interferons, which are thought to play a role in systemic lupus erythematosus disease.

WARNINGS AND PRECAUTIONS

Serious Infections:

Serious and sometimes fatal infections have occurred in patients receiving immunosuppressive agents, including Saphnelo. DO NOT start treatment with Saphnelo if you are currently being treated for an active infection or you have developed an infection while undergoing treatment.

The most common infections are nasopharyngitis, upper respiratory tract infections, bronchitis. Herpes Zoster was seen much more frequently in patients treated with Saphnelo than placebo.

Please discuss preventative vaccinations with your doctor.

Hypersensitivity Reaction:

Serious hypersensitivity reactions (including anaphylaxis) have been reported following Saphnelo administration. Events of angioedema have also been reported. Other hypersensitivity reactions and infusion-related reactions have occurred following the administration of Saphnelo. The incidence of infusion-related reactions was 9.4% in patients on Saphnelo and 7.1% in patients on placebo. Symptoms of mild to moderate reaction were headache, nausea, vomiting, fatigue, and dizziness.

Malignancy:

There is an increased risk of malignancies with the use of immunosuppressants. The impact of Saphnelo on the potential development of malignancies is not known

Immunization:
Avoid the use of live or live-attenuated vaccines in patients treated with Saphnelo

Pregnancy/ Lactation:
There are insufficient data on the use of Saphnelo in pregnant/ lactating women. Discuss risks vs benefits of using this medicine with your doctor if you are pregnant or planning on getting pregnant.

CONTRAINDICATION-
If you have known history of anaphylaxis with Saphnelo.

MEDICATION ADMINISTRATION:
The recommended dosage is 300 mg as an intravenous infusion over a 30-minute period every 4 weeks.

EMERGENCY CONTACTS:

In case of an emergency, please call 911 or go to the nearest emergency room. You can contact our office at (916) 677-4744 from 8:00 am to 5:00 pm Monday – Friday.

I certify that I have read and understand this consent form and agree to receive Saphnelo. I have had an opportunity to discuss this treatment with my physician and ask questions regarding the treatment. I will be given a signed copy of this form for my records.

_____ _____
Patient Name Patient DOB

_____ _____
Patient Signature Date

FINANCIAL RESPONSIBILITY:

Our office will contact your insurance company, and the necessary arrangements will be made for approval of the medication and administration. You may want to follow up with your insurance company also to be sure everything is covered. **Our office does NOT provide a guarantee of coverage for any of these services. If coverage is not provided, YOU WILL BE RESPONSIBLE for any charges incurred for treatment and/or follow-up care.**

_____ _____
Patient signature Date