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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.

Please review detailed PATIENT INFORMATION on SAPHNELO website as well, this information is also attached at the end of this document.

WARNINGS AND PRECAUTIONS

Serious Infections: Serious and sometimes fatal infections have occurred in patients receiving immunosuppressive agents, including SAPHNELO. Do not start treatment during an active infection and consider interrupting therapy in patients who develop a new infection during 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 Including Anaphylaxis: 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 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.

CONTRAINDICATION- 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 emergency, you can contact our office at (503) 297-3384 from 8:00 am to 5:00 pm Monday – Friday, or after hours dial the above number to page your physician or call 911 or go to the emergency room.

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 signature DOB

_____

Date

PATIENT INFORMATION DOCUMENT
From SAPHNELO (anifrolumab-fnia) website
injection, for intravenous use

What is SAPHNELO?

- SAPHNELO is a prescription medicine used to treat adults with moderate to severe systemic lupus erythematosus (SLE or lupus) who are receiving other lupus medicines.
- SAPHNELO contains anifrolumab-fnia which is in a group of medicines called monoclonal antibodies. Lupus is a disease of the immune system (the body system that fights infection). When given together with other medicines for lupus, SAPHNELO may help to reduce your lupus disease activity more than other lupus medicines alone.
- It is not known if SAPHNELO is effective in people with severe active lupus nephritis or central nervous system lupus.
- It is not known if SAPHNELO is safe and effective in children under 18 years of age.

Do not use SAPHNELO if you:

- are allergic to anifrolumab-fnia or any of the ingredients in SAPHNELO. See the end of this Patient Information leaflet for a complete list of ingredients in SAPHNELO.

Before you receive SAPHNELO, tell your healthcare provider about all of your medical conditions, including if you:

- think you have an infection or have infections that keep coming back. You should not receive SAPHNELO if you have an infection unless your healthcare provider tells you to. See “What are the possible side effects of SAPHNELO?”
- are scheduled to receive a vaccination or if you think you may need a vaccination. You should not receive live vaccines during treatment with SAPHNELO.
- have or have had any type of cancer.
- are receiving other biologic medicines or monoclonal antibodies.
- are pregnant or plan to become pregnant. It is not known if SAPHNELO will harm your unborn baby.

Tell your healthcare provider if you are pregnant, think you might be pregnant, or plan to become pregnant during your treatment with SAPHNELO.

- Pregnancy Exposure Registry. If you become pregnant while receiving SAPHNELO, talk to your healthcare provider. A pregnancy exposure registry monitors pregnancy outcomes in women exposed to SAPHNELO. You can find out more information about the registry by calling AstraZeneca at 1-877-693-9268.
- - are breastfeeding or plan to breastfeed. It is not known if SAPHNELO passes into your breast milk. Talk to your healthcare provider about the best way to feed your baby while receiving SAPHNELO.

Tell your healthcare provider about all the medicines you take, including prescription and over-the-counter medicines, vitamins, and herbal supplements. SAPHNELO may affect the way other medicines work, and other medicines may affect how SAPHNELO works.

How will I receive SAPHNELO?

- Your healthcare provider will give you SAPHNELO through a needle placed in a vein (IV or intravenous infusion). It takes about 30 minutes to give you the full dose of SAPHNELO.
- SAPHNELO is usually given 1 time every 4 weeks.
- If you miss an appointment, call your healthcare provider as soon as possible to reschedule your appointment.

What are the possible side effects of SAPHNELO?
SAPHNELO may cause serious side effects, including:

- Serious Infections. SAPHNELO can lower the ability of your immune system to fight infections. You may be at a higher risk of developing respiratory infections and shingles (herpes zoster) during treatment with SAPHNELO. Infections could be serious, leading to hospitalization or death. Tell your healthcare provider right away if you have any of the following symptoms of an infection:
  - fever, sweating, or chills
  - muscle aches
  - cough
  - shortness of breath
  - burning when urinating
  - urinating more often
  - diarrhea or stomach pain
  - warm, red, or painful skin or sores on your body.
- Allergic (hypersensitivity) reactions, including anaphylaxis. Serious allergic reactions can happen during or after you get your SAPHNELO infusion. Tell your healthcare provider or get emergency help right away if you have any of the following symptoms of a serious allergic reaction:
  - swelling of your face, mouth, and tongue
  - breathing problems
  - fainting or dizziness
  - feeling lightheaded (low blood pressure)
- Cancer. SAPHNELO may reduce the activity of your immune system. Medicines that affect the immune system may increase your risk of certain cancers.
- The most common side effects of SAPHNELO include:
  - upper respiratory infections
  - infusion reactions
  - cough
  - bronchitis
  - shingles (herpes zoster)

These are not all of the possible side effects of SAPHNELO. Call your doctor for medical advice about side effects. You may report side effects to FDA at 1-800-FDA-1088.

General information about the safe and effective use of SAPHNELO
Medicines are sometimes prescribed for purposes other than those listed in a Patient Information leaflet. If you would like more
information about SAPHNELO, talk with your healthcare provider. You can ask your pharmacist or healthcare provider for information
about SAPHNELO that is written for health professionals.
What are the ingredients in SAPHNELO?

Active ingredient: anifrolumab-fnia
Inactive ingredients: L-histidine, L-histidine hydrochloride monohydrate, L-lysine hydrochloride, trehalose dihydrate, polysorbate 80 and Water for Injection.