infusioncare
OF COMMUNITY CARE PHYSICIANS

SAPHNELO INFORMED CONSENT FORM

Your physician has recommended a SAPHNELO infusion for the treatment. Before agreeing to this treatment, it is important that you read and understand the following explanation of the SAPHNELO infusion process. This statement will describe the procedure, benefits, discomforts, risks and precautions.

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.

Indications
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.

Dosage and Administration
SAPHNELO is administered by intravenous infusion that will last a minimum of 30 minutes. One should allow sufficient time for pre and post infusion evaluation. We will place an IV in your arm, which may be uncomfortable.

A full clinical response may not be evident for several weeks following the infusion. You should continue to take all of your other medications, unless otherwise indicated by your physician.

Potential Adverse Reactions
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

Prior to using SAPHNELO, please tell your physician or nurse if you (please initial):

_____ Have been previously exposed to tuberculosis (TB)

_____ Have has Hepatitis B or C Infection

_____ Pregnant or breast feeding

_____ Have new symptoms or medical problems

_____ Have had any live vaccinations recently (These include measles, mumps, rubella, oral polio (the injectable polio vaccine is not live), oral typhoid (typhoid injection is not live), BCG, yellow fever)

_____ Any Fever or Current Signs/Symptoms of an Infection

_____ Any Acute Cut, Wound or Rash

I understand all possible side effects from this medication may not have been completely identified and as new information becomes available I will be notified.

I have had the opportunity to fully read, understand and discuss this consent form with my physician and the nurses. By signing this consent, I am agreeing to treatment with SIMPONI ARIA.

_____ _____

Patient's Name Witness' Name

_____ _____

Patient's Signature Witness' Signature

_____ _____

Date Date