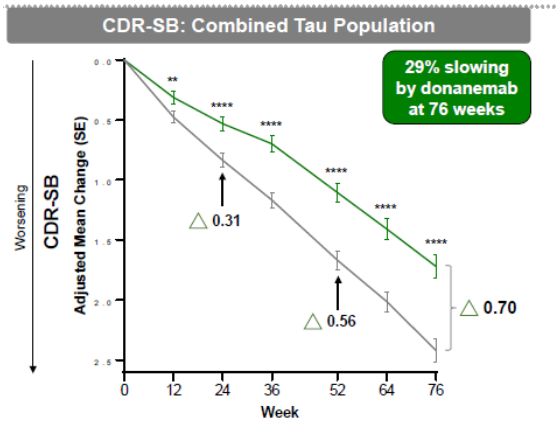
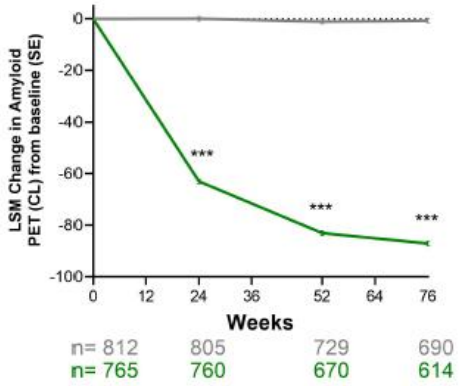
Request and Informed Consent for Donanemab (Kisunla) Intravenous Infusion

I, _____ (date of birth: _____), agree to have Dr. _____ or designees under the doctor's supervision, perform the following intravenous infusion using Donanemab (Kisunla).

Donanemab (Kisunla) is an amyloid beta-directed antibody indicated for the treatment of Alzheimer's disease. This treatment is initiated in patients with mild cognitive impairment or mild dementia stage of disease.

People who have early Alzheimer's disease have a build-up of abnormal toxic protein called amyloid. Donanemab reduces amyloid. As a result, the drug helps people's memory, thinking, and day to day function. This drug is usually safe, but there are important safety risks. Taking this drug is entirely voluntary. No matter your decision, you can change your mind.





I understand and consent to other treatments and procedures that need to be done if conditions are found and judged by the doctor to need immediate treatment during this procedure.

I understand that all medical/surgical procedures carry certain risks. The major risks of the above procedure have been explained to me. I also understand that the practice of medicine is not an exact science and, therefore, no warranty or guarantee on the outcome can be given to me, I understand that full return to prior function may not be achieved. I understand that alternative treatments and their risks have been explained to me.

I understand the proposed therapy is administered intravenously (putting a catheter into a vein to administer therapy). The discomfort associated with venipuncture is minor when the sterile needle enters the skin. The risks of venipuncture also include a bruise. Less commonly, a small blood clot, infection or bleeding may occur at the needle puncture site. When therapy is administered into a vein, there is also a small risk of either infection in the bloodstream or the therapy leaking outside the vein.

It is unknown what effects this therapy may have on an unborn child in a pregnant woman, or on an ability to have children in the future. It is important that both men and women who are being treated with these therapies and who are sexually active, fertile, and who have a fertile partner use birth control.

Donanemab (Kisunla) can cause serious side effects, including:

1. *Amyloid related imaging abnormalities (ARIA)* — Most commonly seen as temporary swelling on an MRI scan. Some people may have small spots of bleeding in their brain. Infrequently larger areas of bleeding in the brain can occur. A gene called APOE4 increases risk of the brain swelling:
    - If you have no APOE4, you are at a low risk (15.7%)
    - If you have one copy of APOE4, you are at a moderate risk (22.6%)
    - If you have two copies of APOE4, you are at a higher risk (40.6%)

A new titration may lower this risk for you. Most people with this type of swelling in the brain do not get symptoms, however, some people may have symptoms such as: headache, confusion, dizziness, vision changes, nausea, and difficulty walking. Rarely serious side effects can occur. This include and are not limited to lethargy, confusion, falls, and seizures. Symptoms can resolve over months, but some patients have very long recoveries. Rarely, some cases of ARIA require cessation of treatment and have long-lasting serious consequences, and in some cases, even prove fatal. You will undergo MRI scans before and during donanemab treatment to check for ARIA.

> ⚠ **CALL THE OFFICE RIGHT AWAY IF YOU HAVE ANY OF THE SYMPTOMS LISTED ABOVE.**

2. *Infusion-related reactions* are a common side effect. You will receive Donanemab (Kisunla) in the infusion suite and nurses will be monitoring you. Let the nurse know if you experience any of the following side effects during your treatment:
    - Fever.
    - Flu-like symptoms (chills, body aches, feeling shaky, joint pain).
    - Nausea or vomiting.
    - Dizziness or lightheadedness.
    - Changes in your heart rate or feeling like your chest is pounding.
    - Difficulty breathing or shortness of breath.

If you have an infusion-related reaction, the nurse will stop your infusion to manage your symptoms and may resume your treatment if or when authorized by your doctor. Some people may experience side effects hours after the infusion. If you experience side effects at home after your infusion, you may call the office number**.**

I acknowledge that the information I have received, as summarized on this form, is sufficient for me to consent to and authorize the therapy described above. I have had the opportunity to ask questions concerning my condition, the therapy, the alternatives, and the risks, and all questions have been answered to my satisfaction.

Patient signature: _____ Date: _____

Physician signature: _____ Date: _____