Fact Sheet for Patients and Caregivers Emergency Use Authorization (EUA) of KINERET® (anakinra) for Coronavirus Disease 2019 (COVID-19)

You are being given this fact sheet because your healthcare provider believes it is necessary to provide you with KINERET for the treatment of coronavirus disease 2019 (COVID-19). KINERET is authorized for emergency use for the treatment of COVID-19 in hospitalized adults with positive results of direct SARS-CoV-2 viral testing with pneumonia requiring supplemental oxygen (low or high-flow oxygen) who are at risk of progressing to severe respiratory failure, and are likely to have an increased blood level of a certain substance called urokinase plasminogen activator receptor (suPAR) that may be a sign of increased risk of worsening of the disease. This fact sheet contains information to help you understand the risks and benefits of taking KINERET you have received or may receive.

The U.S. Food and Drug Administration (FDA) has issued an Emergency Use Authorization (EUA) to make KINERET available during the COVID-19 pandemic (for more details about an EUA please see **"What is an Emergency Use Authorization?"** at the end of this document). KINERET is not FDA-approved for this use. Read this Fact Sheet for information about KINERET and talk to your healthcare provider about your options or if you have any questions. It is your choice for you to take KINERET or stop it at any time.

What is COVID-19?
COVID-19 is an illness caused by a virus called a coronavirus. You can get COVID-19 through close contact with another person who has the virus. COVID-19 illnesses have ranged from very mild (including some with no reported symptoms) to severe, including illness resulting in death. While information so far suggests that most COVID-19 illness is mild, serious illness can happen and may cause some of your other medical conditions to become worse. People of all ages with severe, long lasting (chronic) medical conditions like heart disease, lung disease and diabetes, for example, seem to be at higher risk of being hospitalized for COVID-19.

What is KINERET?
KINERET is a prescription medicine called an interleukin-1 receptor antagonist (IL-1Ra). KINERET is an FDA-approved medicine used to reduce the signs and symptoms and slow the damage of moderate to severe active rheumatoid arthritis (RA) in people age 18 years and older when one or more other medicines for RA have not worked, to treat people with a form of Cryopyrin-Associated Periodic Syndromes (CAPS) called Neonatal-Onset Multisystem Inflammatory Disease (NOMID) and to treat people with Deficiency of Interleukin-1 Receptor Antagonist (DIRA). KINERET is not FDA-approved to treat COVID-19. KINERET is not authorized for COVID-19 patients younger than 18 years of age.

The FDA has authorized under an EUA the emergency use of KINERET for the treatment of COVID-19 in hospitalized adults with positive results of direct SARS-CoV-2 viral testing with pneumonia requiring supplemental oxygen (low or high-flow oxygen) who are at risk of progressing to severe respiratory failure and are likely to have an increased blood level of a certain substance called urokinase plasminogen activator receptor (suPAR) that may be a sign of increased risk of worsening of the disease. For more information on EUA, see the "What is an Emergency Use Authorization (EUA)?" section at the end of this Fact Sheet.

What should I tell my health care provider before I take KINERET?
Tell your healthcare provider if you:

- Have any allergies.
- Have kidney problems.
- Are pregnant or plan to become pregnant.
- Are breastfeeding or plan to breastfeed.
- Have any serious illnesses.
- Are scheduled to receive any vaccines. People using KINERET should not receive live vaccines.
- Are taking any medicines (prescription, over-the-counter, vitamins, or herbal supplements). KINERET and other medicines may affect each other and cause serious side effects. Especially, tell your healthcare provider if you take certain other medicines that affect your immune system called Tumor Necrosis Factor (TNF) blockers or anti-cytokines.

How will I receive KINERET?

- KINERET is given to you by injection under the skin as a single dose 1 time each day for a total of 10 days.
- If you have kidney problems or end stage renal disease (ESRD) you may be given 1 dose every other day, for up to 10 days (up to 5 doses in total).

Who should generally not take KINERET?
Do not take KINERET if:

- You are allergic to proteins made from bacteria called E.coli. Ask your healthcare provider if you are not sure.
- You are allergic to anakinra, the active ingredient in KINERET, or any of the ingredients in KINERET. For a complete list of ingredients in KINERET, refer to the Package Insert for KINERET (anakinra) at www.KineretRx.com

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

- **Allergic reactions.** Stop using KINERET and call your healthcare provider or get emergency help right away if you have any of these symptoms of an allergic reaction: swelling of your face, lips, mouth or tongue, trouble breathing, wheezing, severe

itching skin rash, hives, redness, or swelling outside of the injection site area, dizziness or fainting, fast heartbeat or pounding in your chest (tachycardia), sweating.

- **Low white blood cell count (neutropenia).** KINERET may cause you have a lower number of certain white blood cells (neutrophils). Neutrophils are important in fighting infections. You should have blood tests before starting treatment with KINERET

The most common side effects of KINERET include:

- **Increased levels of liver enzymes:** KINERET may cause you to have increased levels of the liver enzymes as determined after a blood test.
- **Rash.**
- **Injection site skin reactions.** The symptoms of injection site skin reactions may include: redness, swelling, bruising, itching, stinging.

What other treatment choices are there?
Olumiant (baricitinib) and Veklury (remdesivir) are FDA-approved medicines for the treatment of COVID-19 in certain hospitalized patients. Talk with your healthcare provider to see if those therapies are appropriate for you.

Like KINERET, FDA may allow for the emergency use of other medicines to treat people with COVID-19. Go to https://www.fda.gov/emergency-preparedness-and-response/mcm-legal-regulatory-and-policy-framework/emergency-use-authorization for more information on the emergency use of other medicines that are authorized by FDA to treat people with COVID-19. Your healthcare provider may talk with you about other medicines that are used for the treatment of COVID-19 or clinical trials for which you may be eligible.

It is your choice for you to be treated or not to be treated with KINERET. Should you decide not to receive it, it will not change your standard medical care.

What if I am pregnant or breastfeeding?
There is limited experience giving KINERET to pregnant women or breastfeeding mothers. It is unknown if KINERET passes into your breast milk. For a mother and unborn baby, the benefit of receiving KINERET may be greater than the risk from the treatment. If you are pregnant or breastfeeding, discuss your options and specific situation with your healthcare provider.

How do I report side effects with KINERET?
Contact your health care provider if there are any side effects that bother you or do not go away. Report side effects **to FDA MedWatch** at www.fda.gov/medwatch or call 1-800-FDA-1088. You may also report side effects to Sobi by calling 1-866-773-5274

How can I learn more about COVID-19?
- Ask your healthcare provider.
- Visit https://www.cdc.gov/COVID19.
- Contact your local or state public health department.

What is an Emergency Use Authorization (EUA)?
The United States FDA has made KINERET available under an emergency access mechanism called an Emergency Use Authorization (EUA) as a treatment for certain

patients with COVID-19. The EUA is supported by a Secretary of Health and Human Services (HHS) declaration that circumstances exist to justify the emergency use of drugs and biological products during the COVID-19 pandemic.

KINERET for the treatment of COVID-19 in hospitalized adults with positive results of direct SARS-CoV-2 viral testing with pneumonia requiring supplemental oxygen (low or high-flow oxygen) who are at risk of progressing to severe respiratory failure and are likely to have an increased blood level of a certain substance called urokinase plasminogen activator receptor (suPAR) that may be a sign of increased risk of worsening of the disease, has not undergone the same type of review as an FDA-approved product for this indication. In issuing an EUA under the COVID-19 public health emergency, the FDA has determined, among other things, that based on the total amount of scientific evidence available, including data from adequate and well-controlled clinical trials, if available, it is reasonable to believe that the product may be effective for diagnosing, treating, or preventing COVID-19, or a serious or life-threatening disease or condition caused by COVID-19; that the known and potential benefits of the product, when used to diagnose, treat, or prevent such disease or condition, outweigh the known and potential risks of such product; and that there are no adequate, approved and available alternatives.

All of these criteria must be met to allow for the product to be used in the treatment of patients during the COVID-19 pandemic.

The EUA for KINERET is in effect for the duration of the COVID-19 declaration justifying emergency use of this product, unless terminated or revoked (after which the products may no longer be used under the EUA).

This Fact Sheet may be updated as new data become available. The most recent version of this Fact Sheet is available at www.KineretRxHCP.com/EUA for download.

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