KEVZARA® (sarilumab)

KEVZARA is an injectable prescription medicine called an Interleukin-6 (IL-6) receptor blocker. **KEVZARA is used to treat adults with moderately to severely active rheumatoid arthritis (RA) after at least one other medicine called a disease modifying anti-rheumatic drug (DMARD) has been used and did not work well or could not be tolerated.**

KEVZARA is a human monoclonal antibody that binds to the interleukin-6 receptor (IL-6R) and has been shown to inhibit IL-6R mediated signaling. IL-6 is a cytokine in the body that, in excess and over time, can contribute to the inflammation associated with RA.

CLINICAL DATA

The approval of KEVZARA was based on data from approximately 2,900 adults with moderately to severely active RA who had an inadequate response to previous treatment regimens. In clinical trials, KEVZARA demonstrated statistically significant, clinically-meaningful improvements in reducing signs and symptoms, improving physical function, and reducing radiographic progression of structural damage of RA in patients with moderately to severely active RA. KEVZARA can be used as monotherapy or in combination with conventional DMARDs, including methotrexate. Patients treated with KEVZARA are at increased risk for developing serious infections that may lead to hospitalization or death. The most common adverse reactions (occurring in at least 3% of patients treated with KEVZARA in combination with DMARDs vs. placebo in combination with DMARDs) observed with KEVZARA in the clinical studies were neutropenia (7-10% vs. 0.2%), increased alanine aminotransferase (5% vs. 2%), injection site erythema (4-5% vs. 0.9%), upper respiratory infections (3-4% vs. 2%) and urinary tract infections (3% vs. 2%).

ACCESS TO KEVZARA

Sanofi and Regeneron are committed to helping patients in the U.S. who are prescribed KEVZARA gain access to the medicine and receive the support they may need. The companies have launched KevzaraConnect®, a comprehensive and specialized program that provides support services to patients throughout every step of the treatment process. KevzaraConnect will also help eligible patients who are uninsured, lack coverage, or need assistance with their out-of-pocket co-pay costs. Additionally, KevzaraConnect offers personalized support from registered nurses and other specialists who are available 24/7 to speak with patients and help them navigate the complex insurance process. For more information, please call 1-844-Kevzara (1-844-538-9272) or visit www.Kevzara.com.

IMPORTANT SAFETY INFORMATION

KEVZARA can cause serious side effects including:

- **SERIOUS INFECTIONS: KEVZARA is a medicine that affects your immune system. KEVZARA can lower the ability of your immune system to fight infections. Some people have serious infections while using KEVZARA, including tuberculosis (TB), and infections caused by bacteria, fungi, or viruses that can spread throughout the body. Some people have died from these infections.**

Please see additional Important Safety Information on following pages and click here for full Prescribing Information including risk of SERIOUS SIDE EFFECTS and Medication Guide.

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ADMINISTRATION & DOSAGE

KEVZARA is administered by subcutaneous injection and may be used as monotherapy or in combination with methotrexate or other conventional DMARDs to treat RA. The recommended dose of KEVZARA is 200 mg once every two weeks given as a subcutaneous injection.

IMPORTANT SAFETY INFORMATION (Continued)

- Before starting KEVZARA, tell your healthcare provider if you:
  - think you have an infection or have symptoms of an infection, with or without a fever, such as sweats or chills, muscle aches, cough, shortness of breath, blood in phlegm, weight loss, warm, red or painful skin or sores on your body, diarrhea or stomach pain, burning when you urinate or urinating more often than normal or feel very tired; or are being treated for an infection, get a lot of infections or have repeated infections
  - have diabetes, HIV, or a weakened immune system.
  - have TB, or have been in close contact with someone with TB
  - live or have lived, or have traveled to certain parts of the country (such as the Ohio and Mississippi River valleys and the Southwest) where there is an increased chance of getting certain fungal infections (histoplasmosis, coccidioidomycosis, or blastomycosis)
  - have or have had hepatitis
- After starting KEVZARA, call your healthcare provider right away if you have any symptoms of an infection.
- **CHANGES IN CERTAIN LABORATORY TEST RESULTS:** Your healthcare provider should do blood tests before and after starting KEVZARA to check for low neutrophil (white blood cells that help the body fight off bacterial infections) counts, low platelet (blood cells that help with blood clotting and stop bleeding) counts, and an increase in certain liver function tests. Changes in test results are common with KEVZARA and can be severe. You may also have changes in other laboratory tests, such as your blood cholesterol levels.
- **TEARS (PERFORATION) OF THE STOMACH OR INTESTINES:** Some people using KEVZARA get tears in their stomach or intestine. Call your healthcare provider right away if you have fever and stomach (abdominal) pain that does not go away.
- **CANCER:** KEVZARA may increase your risk of certain cancers by changing the way your immune system works. Tell your healthcare provider if you have ever had any type of cancer.
- **SERIOUS ALLERGIC REACTIONS:** Serious allergic reactions can happen with KEVZARA. Get medical attention right away if you have any of the following signs: shortness of breath or trouble breathing; feeling dizzy or faint; swelling of the lips, tongue or face; moderate to severe stomach (abdominal) pain or vomiting; or chest pain.
- Do not use KEVZARA if you are allergic to Sarilumab or any of the ingredients of KEVZARA.
- Before using KEVZARA, tell your healthcare provider if you:
  - have an infection
  - have liver problems
  - have had stomach (abdominal) pain or a condition known as diverticulitis (inflammation in parts of the large intestine) or ulcers in your stomach or intestines
  - recently received or are scheduled to receive a vaccine. People who take KEVZARA should not receive live vaccines.
  - plan to have surgery or a medical procedure
  - are pregnant or plan to become pregnant. It is not known if KEVZARA will harm your unborn baby
  - are breastfeeding or plan to breastfeed. Talk to your healthcare provider about the best way to feed your baby if you use KEVZARA. It is not known if KEVZARA passes into your breastmilk.

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IMPORTANT SAFETY INFORMATION (Continued)

- take any medicines, including prescription and nonprescription medicines, vitamins, and herbal supplements. Especially tell your healthcare provider if you use any other medicines to treat your RA. Using KEVZARA with these medicines may increase your risk of infection.

•The most common side effects include:

- injection site redness
- upper respiratory tract infection
- urinary tract infection
- nasal congestion, sore throat, runny nose

These are not all the possible side effects of KEVZARA. Tell your doctor about any side effect that bothers you or does not go away. You are encouraged to report negative side effects of prescription drugs to the FDA at www.fda.gov/medwatch or call 1-800-FDA-1088 or to Sanofi-Aventis at 1-800-633-1610.

To learn more, talk about KEVZARA with your healthcare provider or pharmacist. The FDA-approved Medication Guide and Prescribing Information can be found at KEVZARA.com or by calling 1-844-KEVZARA (1-844-538-9272).

INDICATION

KEVZARA is an injectable prescription medicine called an Interleukin-6 (IL-6) receptor blocker. KEVZARA is used to treat adults with moderately to severely active rheumatoid arthritis (RA) after at least one other medicine called a disease modifying anti-rheumatic drug (DMARD) has been used and did not work well or could not be tolerated.

Please click here for full Prescribing Information including risk of SERIOUS SIDE EFFECTS and Medication Guide.

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