THE ONLY BIOLOGIC INDICATED FOR POLYMYALGIA RHEUMATICA (PMR)

in adults who have had an inadequate response to corticosteroids (CSs) or who cannot tolerate corticosteroid taper[1]

KEVZARA PMR approval supported by SAPHYR: a phase 3 trial of KEVZARA vs CSs (KEVZARA 200 mg Q2W + 14-week CS taper vs placebo Q2W + 52-week CS taper).[1,2]

SAPHYR=SArilumab in Patients witH polYmyalgia Rheumatica; Q2W=once every 2 weeks.

KEVZARA® (sarilumab) injection 200 mg

INDICATION

KEVZARA® (sarilumab) is indicated for treatment of adult patients with polymyalgia rheumatica (PMR) who have had an inadequate response to corticosteroids or who cannot tolerate corticosteroid taper.

IMPORTANT SAFETY INFORMATION

WARNING: RISK OF SERIOUS INFECTIONS

Patients treated with KEVZARA are at increased risk for developing serious infections that may lead to hospitalization or death. Opportunistic infections have also been reported in patients receiving KEVZARA. Most patients who developed infections were taking concomitant immunosuppressants such as methotrexate or corticosteroids.

Avoid use of KEVZARA in patients with an active infection.

Reported infections include:

- **Active tuberculosis, which may present with pulmonary or extrapulmonary disease. Patients should be tested for latent tuberculosis before KEVZARA use and during therapy. Treatment for latent infection should be initiated prior to KEVZARA use.**
- **Invasive fungal infections, such as candidiasis, and pneumocystis. Patients with invasive fungal infections may present with disseminated, rather than localized, disease.**
- **Bacterial, viral and other infections due to opportunistic pathogens.**

Closely monitor patients for signs and symptoms of infection during treatment with KEVZARA. If a serious infection develops, interrupt KEVZARA until the infection is controlled.

Consider the risks and benefits of treatment with KEVZARA prior to initiating therapy in patients with chronic or recurrent infection.

CONTRAINDICATION

Do not use KEVZARA in patients with known hypersensitivity to sarilumab or any of the inactive ingredients.

WARNINGS AND PRECAUTIONS

- ***Infections.*** Serious and sometimes fatal infections due to bacterial, mycobacterial, invasive fungal, viral, or other opportunistic pathogens have been reported in patients receiving immunosuppressive agents including KEVZARA. Among opportunistic infections, TB, candidiasis, and pneumocystis were reported with KEVZARA.
  - Hold treatment with KEVZARA if a patient develops a serious infection or an opportunistic infection.
  - Patients with latent TB should be treated with standard antimycobacterial therapy before initiating KEVZARA. Consider anti-TB therapy prior to initiation of KEVZARA in patients with a past history of latent or active TB in whom an adequate course of treatment cannot be confirmed, and for patients with a negative test for latent TB but having risk factors for TB infection.
  - Consider the risks and benefits of treatment prior to initiating KEVZARA in patients who have: chronic or recurrent infection, a history of serious or opportunistic infections, underlying conditions that may predispose them to infection, been exposed to TB, or lived in or traveled to areas of endemic TB or endemic mycoses.
  - Viral reactivation has been reported with immunosuppressive biologic therapies. Cases of herpes zoster were observed in clinical studies with KEVZARA.
- ***Laboratory Abnormalities.*** Treatment with KEVZARA was associated with decreases in absolute neutrophil counts (including neutropenia), and platelet counts; and increases in transaminase levels and lipid parameters (LDL, HDL cholesterol, and/or triglycerides). Increased frequency and magnitude of these elevations were observed when potentially hepatotoxic drugs (e.g., MTX) were used in combination with KEVZARA. Assess neutrophil count, platelet count, and ALT/AST levels prior to initiation with KEVZARA. Monitor these parameters 4 to 8 weeks after start of therapy and every 3 months thereafter. Assess lipid parameters 4 to 8 weeks after start of therapy, then at 6 month intervals.
- ***Gastrointestinal Perforation.*** GI perforation risk may be increased with concurrent diverticulitis or concomitant use of NSAIDs or corticosteroids. Gastrointestinal perforations have been reported in clinical studies, primarily as complications of diverticulitis. Promptly evaluate patients presenting with new onset abdominal symptoms.
- ***Immunosuppression.*** Treatment with immunosuppressants may result in an increased risk of malignancies. The impact of treatment with KEVZARA on the development of malignancies is not known but malignancies have been reported in clinical studies.
- ***Hypersensitivity Reactions.*** Hypersensitivity reactions have been reported in association with KEVZARA. Hypersensitivity reactions that required treatment discontinuation were reported in 0.3% of patients in controlled RA trials. Injection site rash, rash, and urticaria were the most frequent hypersensitivity reactions. Advise patients to seek immediate medical attention if they experience any symptoms of a hypersensitivity reaction. If anaphylaxis or other hypersensitivity reaction occurs, stop administration of KEVZARA immediately. Do not administer KEVZARA to patients with known hypersensitivity to sarilumab.
- ***Active Hepatic Disease and Hepatic Impairment.*** Treatment with KEVZARA is not recommended in patients with active hepatic disease or hepatic impairment, as treatment with KEVZARA was associated with transaminase elevations.

Please see additional Important Safety Information on following page and click here to see full Prescribing Information, including Boxed WARNING.

KEVZARA OFFERS EVERY-2-WEEK DOSING

FOR PATIENTS WITH PMR[1]

- The recommended dosage of KEVZARA is 200 mg once every 2 weeks given as a subcutaneous injection, in combination with a tapering course of systemic CSs*
- KEVZARA can be used as monotherapy following discontinuation of CSs
- No dose adjustments are recommended based on age, gender, race, or weight

DOSING CONSIDERATIONS FOR PATIENTS WITH PMR

RECOMMENDED DOSAGE MODIFICATIONS[1]

- Discontinue KEVZARA in patients with PMR who develop the following laboratory abnormalities:
  - Neutropenia (ANC below 1000 per mm^3 at the end of the dosing interval)
  - Thrombocytopenia (platelet count below 100,000 per mm^3)
  - AST or ALT elevations 3 times above the ULN
- Dosage modifications have not been studied in patients with PMR with these conditions
- If a patient with PMR develops a serious infection or an opportunistic infection, hold treatment with KEVZARA until the infection is controlled

GENERAL CONSIDERATIONS FOR ADMINISTRATION[1]

- Avoid using KEVZARA with biological DMARDs because of the possibility of increased immunosuppression and increased risk of infection
- KEVZARA initiation is not recommended in patients with an ANC below 2000 per mm^3, platelet count below 150,000 per mm^3, or who have ALT or AST above 1.5 times the ULN
- KEVZARA should not be administered to patients with active TB or other active infections

See Prescribing Information for full dosing instructions.

KEVZARAconnect®

KevzaraConnect® provides eligible patients support for getting started with and saving on KEVZARA.

Scan to learn more

*Dosing of CSs may vary.

ALT=alanine aminotransferase; ANC=absolute neutrophil count; AST=aspartate aminotransferase; DMARD=disease-modifying antirheumatic drug; TB=tuberculosis; ULN=upper limit of normal.

IMPORTANT SAFETY INFORMATION (cont'd)

WARNINGS AND PRECAUTIONS (cont'd)

- ***Live Vaccines.*** Avoid concurrent use of live vaccines during treatment with KEVZARA due to potentially increased risk of infections. No data are available on the secondary transmission of infection from persons receiving live vaccines to patients receiving KEVZARA. Prior to initiating treatment, it is recommended that all patients be brought up to date with all immunizations in agreement with current immunization guidelines.

ADVERSE REACTIONS

- **For Polymyalgia Rheumatica:** Serious adverse reactions of neutropenia occurred in 2 patients (3.4%) in the KEVZARA group compared to none in the placebo group. The proportion of patients with serious infections was similar in the KEVZARA group (5.1%) compared to the placebo group (5.2%). The common adverse reactions occurring in ≥5% of patients treated with KEVZARA were neutropenia, leukopenia, constipation, rash pruritic, myalgia, fatigue, and injection site pruritus.

DRUG INTERACTIONS

- Exercise caution when KEVZARA is co-administered with CYP substrates with a narrow therapeutic index (e.g. warfarin or theophylline), or with CYP3A4 substrates (e.g. oral contraceptives or statins) as there may be a reduction in exposure which may reduce the activity of the CYP3A4 substrate.
- Elevated interleukin-6 (IL-6) concentration may down-regulate CYP activity such as in patients with RA and hence increase drug levels compared to subjects without RA. Blockade of IL-6 signaling by IL-6Rα antagonists such as KEVZARA might reverse the inhibitory effect of IL-6 and restore CYP activity, leading to altered drug concentrations.

USE IN SPECIFIC POPULATIONS

- KEVZARA should be used in pregnancy only if the potential benefit justifies the potential risk to the fetus. Because monoclonal antibodies could be excreted in small amounts in human milk, the benefits of breastfeeding and the potential adverse effects on the breastfed child should be considered along with the mother's clinical need for KEVZARA.
- Use caution when treating the elderly.

Advise patients to read the FDA-approved patient labeling (Medication Guide and Instructions for Use).

Please see additional Important Safety Information on front page and click here to see full Prescribing Information, including Boxed WARNING.

References: 1. KEVZARA [prescribing information]. Morristown, NJ: Sanofi/Regeneron Pharmaceuticals, Inc. **2.** Spiera R, Unizony S, Warrington KJ, et al. Resolution of PMR signs and symptoms in patients treated with sarilumab: a phase 3, multicenter, randomized, double blind, placebo controlled trial (SAPHYR) in relapsing PMR. Poster presented at the American College of Rheumatology Convergence; November 10-14, 2022; Philadelphia, PA.

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