This material was developed by Sanofi Genzyme, as part of the risk minimization plan for KEVZARA™.
It is not intended for promotional use.

KEVZARA (sarilumab) Education/Discussion Guide

INDICATION

KEVZARA (sarilumab) is indicated in the treatment of adult patients with moderately to severely active rheumatoid arthritis (RA) who have had an inadequate response or intolerance to one or more biologic or non-biologic Disease-Modifying Anti-Rheumatic Drugs (DMARDs).

Dear Healthcare Professional:

This Education/Discussion Guide is provided to assist you in the optimal use of KEVZARA (sarilumab) for the treatment of adult patients with rheumatoid arthritis. It will facilitate the discussion with your patient and help you determine specific actions to take to minimize the important risks listed below.

SERIOUS INFECTIONS

- Do not administer KEVZARA in patients with an active infection, including localized infections. Patients should be tested for latent tuberculosis infection prior to initiating treatment with KEVZARA.
- Discuss with your patient the risk of infections/serious infections/viral reactivation, including the need to contact their doctor in case of signs or symptoms of infection, or if the patient takes other medicines that affect the immune system.
- Hold treatment with KEVZARA if a patient develops a serious infection or an opportunistic infection. Treatment with KEVZARA may be reinitiated when the patient has recovered from infection.

LABORATORY MONITORING

Prior to initiating treatment with KEVZARA, it is recommended that appropriate baseline laboratory parameters be measured.

NEUTROPHILS

- Treatment with KEVZARA was associated with a higher incidence of decrease in absolute neutrophil count (ANC). Decrease in ANC was not associated with a higher incidence of infections, including serious infections.
- Initiating treatment with KEVZARA is not recommended in patients with a low neutrophil count, i.e., ANC less than 2 x 10^9/L.
- Monitor neutrophil count 4 to 8 weeks after start of therapy and approximately every 3 months thereafter. In patients who develop an ANC between 0.5-1 x 10^9/L, hold treatment with KEVZARA until > 1 x 10^9/L. KEVZARA can then be resumed at 150 mg every 2 weeks and increased to 200 mg every 2 weeks as clinically appropriate. In patients who develop an ANC less than 0.5 x 10^9/L, discontinue treatment with KEVZARA.

PLATELET COUNT

- Treatment with KEVZARA was associated with a reduction in platelet counts in clinical studies. Reduction in platelets was not associated with bleeding events.
- Initiating treatment with KEVZARA is not recommended in patients with a platelet count below 150 x 10^9/L.
- Monitor platelets 4 to 8 weeks after start of therapy and approximately every 3 months thereafter. In patients

who develop platelet count between 50-100 x 10^9/L, hold treatment with KEVZARA until >100 x 10^9/L. KEVZARA can then be resumed at 150 mg every 2 weeks and increased to 200 mg every 2 weeks as clinically appropriate. In patients who develop a platelet count **less than 50 x 10^9/L, if confirmed by repeat testing, discontinue treatment** with KEVZARA.

LIVER ENZYMES

- Treatment with KEVZARA was associated with a higher incidence of transaminase elevations. These elevations were transient and did not result in any clinically evident hepatic injury in clinical studies. Increased frequency and magnitude of these elevations were observed when potentially hepatotoxic medications (e.g., MTX) were used in combination with KEVZARA.
- Initiating treatment with KEVZARA is not recommended in patients with elevated transaminases, **ALT or AST greater than 1.5 x ULN**.
- Monitor ALT and AST levels 4 to 8 weeks after start of therapy and approximately every 3 months thereafter. In patients who develop ALT > 3 to ≤ 5 x ULN, hold treatment with KEVZARA until < 3 x ULN. KEVZARA can then be resumed at 150 mg every 2 weeks and increased to 200 mg every 2 weeks as clinically appropriate. In patients who develop **ALT greater than 5 x ULN, discontinue treatment** with KEVZARA.

LIPID ABNORMALITIES

- Treatment with KEVZARA was associated with increases in lipid parameters such as LDL cholesterol, HDL cholesterol and/or triglycerides.
- Assess lipid parameters approximately 4 to 8 weeks following initiation of KEVZARA, then at approximately 6 month intervals.
- Manage patients according to clinical guidelines for the management of hyperlipidemia.

GASTROINTESTINAL PERFORATIONS

- Use KEVZARA with caution in patients who may be at increased risk for gastrointestinal perforation. Promptly evaluate patients presenting with new onset abdominal symptoms for early identification of GI perforation.

VACCINATIONS

Avoid concurrent use of live vaccines during treatment with KEVZARA as clinical safety has not been established. The interval between live vaccinations and initiation of KEVZARA therapy should be in accordance with current vaccination guidelines regarding immunosuppressive agents.

This Education/Discussion Guide is not a comprehensive description of the risks of KEVZARA or a comprehensive guide to recommended monitoring and dosage modifications. Refer to the full Product Monograph (PM) for extended prescribing recommendations.

REPORTING ADVERSE EVENTS

Please report to Sanofi Genzyme any medication errors and/or adverse events suspected to be associated with the use of KEVZARA by telephone at 1-800-589-6215 or by email at canada.pharmacovigilance@sanofi.com.

For additional medical information, please call Sanofi Genzyme at 1-800-589-6215. This information is also posted on the Sanofi Genzyme website. The KEVZARA PM can be found at sanofigenzyme.ca or by contacting Sanofi Genzyme at 1-800-589-6215.