KEVZARA MONOTHERAPY IN RA:
HEAD-TO-HEAD VS ADALIMUMAB IN THE MONARCH TRIAL AND POST-ADALIMUMAB SWITCH OUTCOMES IN THE MONARCH OLE

KEVZARA® (sarilumab) injection 200 mg

STUDIES INCLUDED:

1

MONARCH Phase 3 trial:

Burmester GR, Lin Y, Patel R, et al. *Ann Rheum Dis*. 2017;76(5):840-847.

2

MONARCH OLE (up to 48 weeks):

Burmester GR, Strand V, Rubbert-Roth A, et al. *RMD Open*. 2019;5:e001017. doi:10.1136/rmdopen-2019-001017

3

MONARCH OLE (up to 252 weeks):

Burmester GR, Strand V, Kivitz AJ, et al. *Rheumatology (Oxford)*. 2023;62(10):3268-3279.

INDICATION

KEVZARA (sarilumab) is indicated for treatment of:

- adult patients with moderately to severely active rheumatoid arthritis (RA) who have had an inadequate response or intolerance to one or more disease-modifying antirheumatic drugs (DMARDs).

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.**

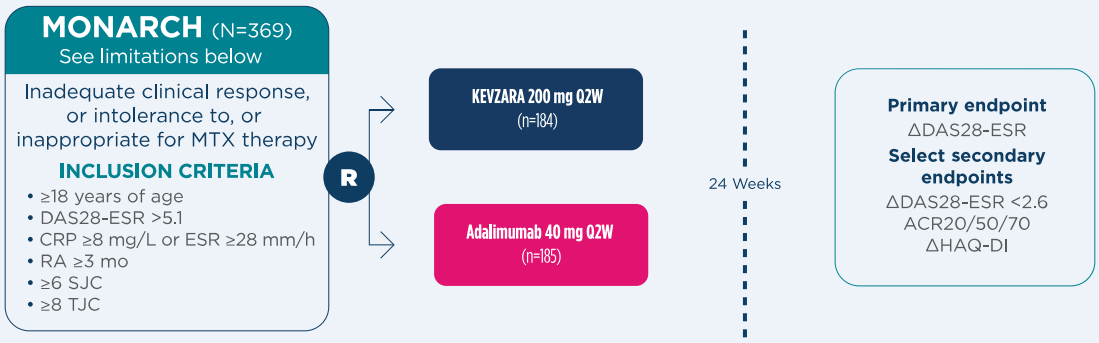
Closely monitor patients for signs and symptoms of infection during treatment with KEVZARA. If a serious infection develops, interrupt KEVZARA until the infection is controlled.

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

Please see Important Safety Information throughout and click here for full **Prescribing Information**, including **Boxed WARNING**.

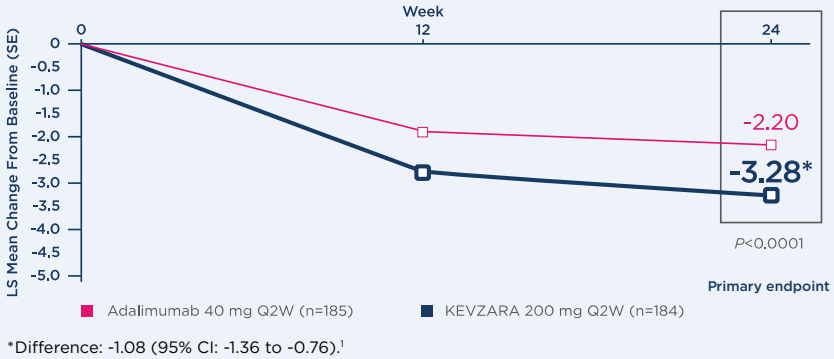
The MONARCH head-to-head superiority trial measured effect on disease activity, physical function, and clinical response with KEVZARA vs adalimumab[1]

KEVZARA® (sarilumab) injection 200 mg

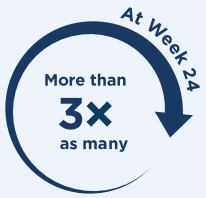


In a head-to-head trial with adalimumab, KEVZARA had 3× as many patients achieve low disease activity[1]

MONARCH (MTX-IR): Change in DAS28-ESR at Week 24[1]



*Difference: -1.08 (95% CI: -1.36 to -0.76).[1]



KEVZARA patients achieved low disease activity (DAS28-ESR <2.6) vs adalimumab monotherapy[1]

(26.6% vs 7.0%; *P*<0.0001)

See pivotal combination therapy data on pages 6 and 7

At 24 weeks, 26.6% of patients receiving KEVZARA as monotherapy achieved DAS28-ESR <2.6 (low disease activity) versus 7% of patients receiving adalimumab as monotherapy[1]

MONARCH study context and limitations[1,2]

Use of adalimumab

- Adalimumab and KEVZARA have different indications and can be used differently in clinical practice[2,3]
- Dose escalation from adalimumab 40 mg Q2W to 40 mg QW was permitted after Week 16 in patients who had not achieved at least 20% improvement in TJC and SJC. By Week 24, dosing for 8.6% of patients on adalimumab was adjusted[1]

Study limitations

- KEVZARA and adalimumab can be used as monotherapy or in combination with nonbiologic DMARDs. In MONARCH, both agents were only used as monotherapy[2,3]
- The efficacy of KEVZARA monotherapy has not been compared to that of KEVZARA + MTX or adalimumab + MTX[2,3]
- MONARCH did not evaluate radiographic outcomes in either treatment group

Given the limitations and context described above, caution should be used when interpreting monotherapy data.

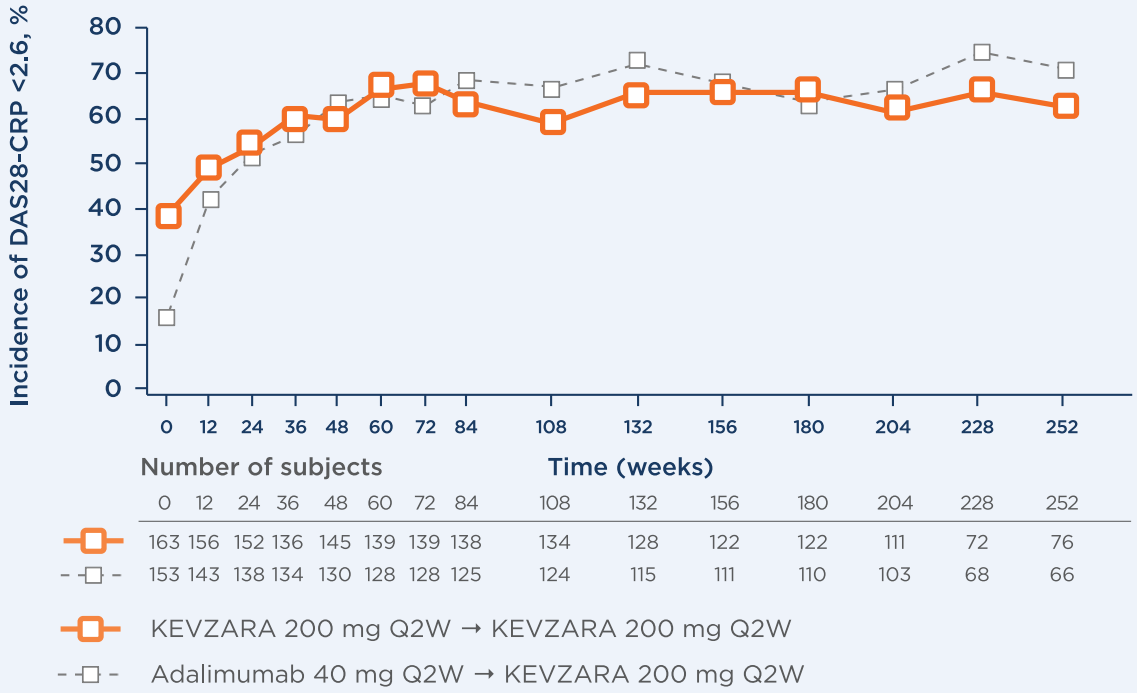
ACR20, American College of Rheumatology 20% improvement criteria; ACR50, American College of Rheumatology 50% improvement criteria; ACR70, American College of Rheumatology 70% improvement criteria; CRP, C-reactive protein; DAS28-ESR, Disease Activity Score-28-erythrocyte sedimentation rate; DMARDs, disease-modifying antirheumatic drugs; ESR, erythrocyte sedimentation rate; FACIT, Functional Assessment of Chronic Illness Therapy; HAQ-DI, Health Assessment Questionnaire-Disability Index; MTX, methotrexate; OLE, open-label extension; QW, once a week; Q2W, once every 2 weeks; RA, rheumatoid arthritis; SJC, swollen joint count; TJC, tender joint count.

In the MONARCH OLE, clinical remission (DAS28-CRP <2.6) was maintained over 4 years with KEVZARA monotherapy[4]

KEVZARA® (sarilumab) injection 200 mg

MONOTHERAPY OPEN-LABEL EXTENSION DATA

Clinical remission data (DAS28-CRP <2.6) over 4 years[4]*



***Measures of remission do not imply drug-free remission or complete absence of disease.**

Given the limitations of OLE data, caution should be used when interpreting these data. There are limitations associated with open-label study design, including decreasing sample size and potential continued involvement of responders and attrition of non-responders. Data presented are descriptive in nature and no statistical comparisons are made.

47% of patients in the switch group (n=155) showed improvement in disease activity (DAS28-ESR ≥1.2) within 12 weeks of switching from adalimumab to KEVZARA in the OLE ITT population (95% CI: 39.2 to 55.0)*[5]

Changes in disease activity were measured in both patients who continued treatment with KEVZARA monotherapy and in those who switched treatment from adalimumab to KEVZARA.

DAS28-CRP, Disease Activity Score 28-C-reactive protein; ITT, intent to treat; OLE, open-label extension; Q2W, once every 2 weeks.

IMPORTANT SAFETY INFORMATION (cont'd)

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. The most frequently observed serious infections with KEVZARA in RA patients included pneumonia and cellulitis.
  - o Hold treatment with KEVZARA if a patient develops a serious infection or an opportunistic infection.
  - o 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.

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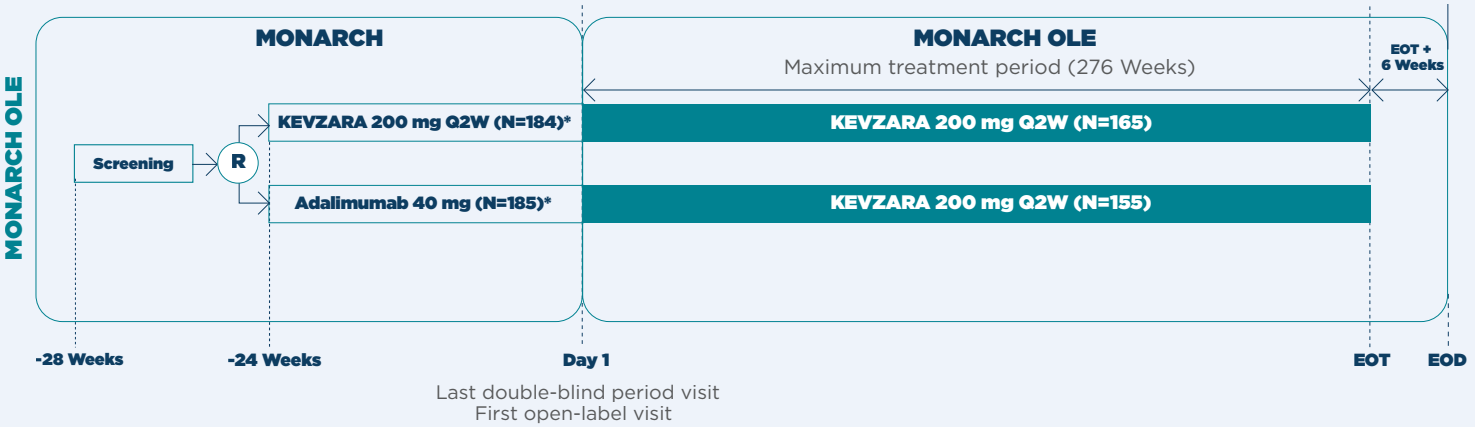
Monotherapy open-label extension study design and limitations[4]



*Patients who rolled over to open-label extension period.[5]

Open-Label Extension (OLE) Study Design: A 276-week open-label extension of the randomized, double-blind, double-dummy Phase 3 superiority study extension designed to assess the safety and efficacy of long-term continuous KEVZARA monotherapy and switching from adalimumab monotherapy to KEVZARA monotherapy in 320 adult patients who completed the MONARCH study. Primary endpoint was safety. Secondary endpoints included DAS28-ESR, DAS28-CRP, HAQ-DI, CDAI, SDAI, and ACR20/50/70.[4,5]

MONARCH long-term study context and limitations

OLE and additional study context

- Long-term safety analysis included all patients who received at least 1 dose of KEVZARA monotherapy
- Analysis of clinical data was based on all available data as observed
- Data presented are descriptive in nature and no statistical comparisons are made
- OLE studies tend to include patients who respond to treatment and exclude those who discontinue treatment for any reason. As such, evaluating long-term efficacy using continuous variables can be influenced by progressively smaller numbers of patients remaining in the study

Given the limitations and context described above, caution should be used in interpreting OLE data. There are limitations associated with open-label study designs, including decreasing sample size and potential continued involvement of responders and attrition of non-responders. Data presented are descriptive in nature and no statistical comparisons are made.

ACR20, American College of Rheumatology 20% improvement criteria; ACR50, American College of Rheumatology 50% improvement criteria; ACR70, American College of Rheumatology 70% improvement criteria; CDAI, Clinical Disease Activity Index; DAS28-CRP, Disease Activity Score 28-C-reactive protein; DAS28-ESR, Disease Activity Score-28-erythrocyte sedimentation rate; EOD, end of study design; EOT, end of study treatment; HAQ-DI, Health Assessment Questionnaire-Disability Index; Q2W, once every 2 weeks; SDAI, Simple Disease Activity Index.

IMPORTANT SAFETY INFORMATION (cont'd)

WARNINGS AND PRECAUTIONS (cont'd)

- 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.

MONARCH monotherapy: no new safety signals compared to safety data from KEVZARA combination therapy pivotal trials

Overall, KEVZARA monotherapy long-term safety was studied in 471 patients, with more than 1700 patient years of exposure, and data were consistent with MONARCH studies[6]

KEVZARA® (sarilumab) injection 200 mg

Long-term monotherapy safety
Including: MONARCH (MTX-IR) and MONARCH long-term safety populations[6,7*†]

	Randomized, Controlled Population		Long-term Safety Population
Adverse Event	**Adalimumab 40 mg Q2W[‡] n=184** % (nE/100 PY)	**KEVZARA 200 mg Q2W n=184** % (nE/100 PY)	**KEVZARA Any Dose n=471** % (nE/100 PY)
Cumulative total TEAE observation period, years[§]	80.5	80.1	1768.9
Any TEAE	63.6% (326.9)	64.1% (462.0)	89.4% (171.0)
Serious TEAE	6.5% (14.9)	4.9% (18.7)	19.5% (8.6)
TEAE leading to discontinuation	7.1% (19.9)	6.0% (21.2)	16.8% (5.3)
TEAE leading to death[‖]	0% (0)	0.5% (3.7)	2.3% (0.9)
Infections	27.7% (82.0)	28.8% (86.2)	58.0% (44.2)
Serious infections[¶]	1.1% (2.5)	1.1% (2.5)	4.5% (1.5)
Bronchitis	3.8% (8.7)	6.5% (18.7)	13.0% (5.6)
Nasopharyngitis	7.6% (18.6)	6.0% (13.7)	17.0% (8.4)
Upper respiratory tract infection	3.8% (11.2)	1.6% (3.7)	12.1% (4.8)
Neutropenia	0.5% (1.2)	13.6% (54.9)	21.2% (16.5)
Headache	6.5% (17.4)	3.8% (11.2)	6.6% (2.9)
Rheumatoid arthritis	3.8% (8.7)	0.5% (1.2)	9.6% (4.2)
Injection site erythema	3.3% (8.7)	7.6% (87.4)	8.3% (17.0)
ALT increase	3.8% (11.2)	3.8% (8.7)	7.4% (2.4)
Accidental overdose[#]	6.0% (14.9)	3.3% (7.5)	14.4% (5.0)
Dyslipidemia[**]	4.3% (9.9)	1.6% (3.7)	5.5% (1.5)

Mean exposure in the long-term safety population was 3.7 years (max 6.2 years)[7]
- 222 patients (47.1%) were treated for >240 weeks (4.6 years)

In MONARCH, the safety profiles of KEVZARA and adalimumab were generally comparable, except for neutropenia and injection site erythema for KEVZARA and headache and RA for adalimumab.[6]

Safety observations in the long-term population were generally consistent with those in the randomized, controlled population.[6]

nE/100 PY is the exposure-adjusted event rate.[4]

*Adverse events reported for the long-term safety population were selected based on occurrence in ≥3% of patients in the randomized, controlled population in any treatment group.[1]

†111 patients from the KEVZARA ONE study population were included in these long-term monotherapy safety data.[4]

‡One patient was randomized, but not treated, in the adalimumab group and was not included in the safety population.[1]

§TEAE period from day of first treatment dose to 60 days after the last treatment dose.[6]

‖In the randomized trial, 1 patient in the KEVZARA group died of acute cardiac failure secondary to aortic dissection and papillary muscle rupture on Day 36.[1]

¶In the randomized trial, 1 patient receiving KEVZARA was diagnosed with infective bursitis and another patient was diagnosed with mastitis, and 1 patient receiving adalimumab was diagnosed with bacterial arthritis and another patient was diagnosed with a respiratory tract infection.[1]

#Protocol was defined as ≥2 doses within 11 calendar days or within 6 days for adalimumab-treated patients who switched to weekly dosing.[1]

**Dyslipidemia was defined by standardized MedDRA query.[1]

AE, adverse event; ALT, alanine aminotransferase; MTX-IR, methotrexate inadequate response; nE, number of events; PY, patient years; Q2W, once every 2 weeks; RA, rheumatoid arthritis; TEAE, treatment-emergent adverse event.

Incidence rate of AEs was generally stable over time, with no indication of increased incidence rate.[2]

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KEVZARA demonstrated robust clinical remission in TNF-IR and MTX-IR patients in pivotal trials

KEVZARA® (sarilumab) injection 200 mg

29% **of TNF-IR patients achieved clinical remission** (DAS28-CRP <2.6) with KEVZARA 200 mg + DMARD(s) at Week 24 vs 7% with placebo + DMARD(s)[9]

34% **of MTX-IR patients achieved clinical remission** (DAS28-CRP <2.6) with KEVZARA 200 mg + MTX at Week 24 vs 10% with placebo + MTX[8]

Measures of remission do not imply drug-free remission or complete absence of disease

PIVOTAL TRIAL DATA[2,8,9]:

ACR20 response in MTX-IR (MOBILITY trial) and TNF-IR (TARGET trial)

ACR20 response at Week 24 was the primary endpoint in MOBILITY (MTX-IR) and TARGET (TNF-IR). Patients achieved:

- 66%* with KEVZARA 200 mg + MTX compared to 33% with placebo + MTX (MOBILITY)
- 61%* with KEVZARA 200 mg + DMARD(s) compared to 34% with placebo + DMARD(s) (TARGET)

ΔHAQ-DI IN MOBILITY AND TARGET (CO-PRIMARY ENDPOINT)

Mean change from baseline in HAQ-DI at Week 16 in MOBILITY and Week 12 in TARGET was a co-primary endpoint.

- -0.58* with KEVZARA 200 mg + MTX compared to -0.30 with placebo + MTX (MOBILITY)
- -0.49† with KEVZARA 200 mg + DMARD(s) compared to -0.29 with placebo + DMARD(s) (TARGET)

In MOBILITY, ΔmTSS from baseline at Week 52 was 0.25 with KEVZARA 200 mg vs 2.78 with placebo* (CO-PRIMARY ENDPOINT)

- KEVZARA 200 mg + MTX provided an absolute difference of -2.52 units (CI: -3.38, -1.66) in mean ΔmTSS relative to placebo + MTX

*P<0.0001; †P<0.001.

Study designs for pivotal trials

MOBILITY Study Design: A 52-week, randomized, double-blind, placebo-controlled, multicenter study (N=1197) assessing the efficacy and safety of KEVZARA 200 mg + MTX and 150 mg + MTX in patients with moderate to severe active RA (duration of ≥3 months) who had been on MTX 10 mg to 25 mg/week ≥6 weeks. Primary endpoints were reduction of signs and symptoms (ACR20) at 24 weeks, change in van der Heijde mTSS at 52 weeks, and change from baseline in HAQ-DI at 16 weeks. After Week 16 in MOBILITY, patients with an inadequate response could have been treated with open-label KEVZARA 200 mg every 2 weeks.[8]

TARGET Study Design: A 24-week, randomized, double-blind, parallel group, placebo-controlled, multicenter study (N=546) assessing the efficacy and safety of KEVZARA 200 mg and 150 mg added to background conventional DMARD(s) in adult patients with moderate to severe active RA (≥6 months duration) with inadequate response and/or intolerance to 1 or more TNF antagonists, when administered with background conventional DMARD(s). Primary endpoints were reduction of signs and symptoms (ACR20) at 24 weeks and change from baseline in HAQ-DI at 12 weeks. After Week 12 in TARGET, patients with an inadequate response could have been treated with open-label KEVZARA 200 mg every 2 weeks.[9]

IMPORTANT SAFETY INFORMATION (cont'd)

WARNINGS AND PRECAUTIONS (cont'd)

- ***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.

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KEVZARA has an established RA safety profile as a combination therapy[2,6]

KEVZARA (sarilumab) injection 200 mg

Common adverse reactions in pre-rescue, placebo-controlled trials[2]*

Preferred Term	Placebo + DMARD(s) N=579	KEVZARA 150 mg + DMARD(s) N=579	KEVZARA 200 mg + DMARD(s) N=582
Neutropenia	0.2%	7%	10%
ALT increased	2%	5%	5%
Injection site erythema	0.9%	5%	4%
Injection site pruritus	0.2%	2%	2%
Upper respiratory tract infection	2%	4%	3%
Urinary tract infection	2%	3%	3%
Hypertriglyceridemia	0.5%	3%	1%
Leukopenia	0%	0.9%	2%

*Adverse reactions occurring in ≥2% of patients administered KEVZARA 200 mg or KEVZARA 150 mg + DMARD(s) and greater than observed in patients on placebo + DMARD(s).

- Medically relevant AE occurring at an incidence of less than 2% in patients with RA treated with KEVZARA in controlled studies was oral herpes[2]
- Decrease in ANC was not associated with higher incidence of infections, including serious infections[2]
- In the long-term safety population, the overall rates of serious infections, GI perforations, neutrophil counts, platelet counts, and lipid parameters were consistent with what was observed in the placebo-controlled trials[2]

ACR20, American College of Rheumatology 20% improvement criteria; ALT, alanine aminotransferase; ANC, absolute neutrophil count; DAS28-CRP=Disease Activity Score 28-C-reactive protein; DMARD, disease-modifying antirheumatic drug; GI, gastrointestinal; RA, rheumatoid arthritis; HAQ-DI, Health Assessment Questionnaire-Disability Index; MTX, methotrexate; mTSS, modified Total Sharp Score; MTX-IR, methotrexate inadequate response; TNF-IR, tumor necrosis factor inhibitor inadequate response; TNFi; tumor necrosis factor.

IMPORTANT SAFETY INFORMATION (cont'd)

WARNINGS AND PRECAUTIONS (cont'd)

- ***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.
- ***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 Rheumatoid Arthritis:** The most common serious adverse reactions were infections. The most frequently observed serious infections included pneumonia and cellulitis. The most common adverse reactions (occurred in at least 3% of patients treated with KEVZARA + DMARDs) are neutropenia, increased ALT, injection site erythema, upper respiratory infections, and urinary tract infections.

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.

Please see Important Safety Information throughout and click here for full Prescribing Information, including Boxed WARNING.

MONARCH Phase 3 trial:
Efficacy and safety of sarilumab monotherapy versus adalimumab monotherapy for the treatment of patients with active rheumatoid arthritis (MONARCH): a randomised, double-blind, parallel-group phase III trial

CLICK HERE FOR ACCESS TO FULL PUBLICATION

MONARCH OLE (up to 48 weeks):
Safety and efficacy of switching from adalimumab to sarilumab in patients with rheumatoid arthritis in the ongoing MONARCH open label extension

CLICK HERE FOR ACCESS TO FULL PUBLICATION

MONARCH OLE (up to 252 weeks):
Long-term safety and efficacy of sarilumab with or without background csDMARDs in rheumatoid arthritis

CLICK HERE FOR ACCESS TO FULL PUBLICATION

IMPORTANT SAFETY INFORMATION (cont'd)

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).

csDMARDs, conventional synthetic DMARDs; OLE, open-label extension.

Please see Important Safety Information throughout and click here for full Prescribing Information, including Boxed WARNING.

References: 1. Burmester GR, Lin Y, Patel R, et al. Efficacy and safety of sarilumab monotherapy versus adalimumab monotherapy for the treatment of patients with active rheumatoid arthritis (MONARCH): a randomized, double-blind parallel-group phase III trial. *Ann Rheum Dis.* 2017;76(5):840-847. **2.** KEVZARA [prescribing information]. Bridgewater, NJ: Sanofi/Regeneron Pharmaceuticals, Inc. **3.** Humira [prescribing information]. North Chicago, IL: AbbVie, Inc. **4.** Burmester GR, Strand V, Kivitz AJ, et al. Long-term safety and efficacy of sarilumab with or without background csDMARDs in rheumatoid arthritis. *Rheumatology (Oxford).* 2023;62(10):3268-3279. **5.** Burmester GR, Strand V, Rubbert-Roth A, et al. Safety and efficacy of switching from adalimumab to sarilumab in patients with rheumatoid arthritis in the ongoing MONARCH open-label extension. *RMD Open.* 2019;5:e001017. doi:10.1136/rmdopen-2019-001017 **6.** Data on File. Bridgewater, NJ: Sanofi/Regeneron. Summary of treatment emergent adverse events - sarilumab MONARCH and monotherapy population (pool 3). April 2023. **7.** Data on File. Bridgewater, NJ: Sanofi/Regeneron. Integrated Summary of Safety: Appendix 1.3. June 2021. **8.** Genovese MC, Fleischmann R, Kivitz AJ, et al. Sarilumab plus methotrexate in patients with active rheumatoid arthritis and inadequate response to methotrexate: results of a phase III study. *Arthritis Rheumatol.* 2015;67(6):1424-1437. **9.** Fleischmann R, Adelsberg JV, Lin Y, et al. Sarilumab and nonbiologic disease-modifying antirheumatic drugs in patients with active rheumatoid arthritis and inadequate response or intolerance to tumor necrosis factor inhibitors. *Arthritis Rheumatol.* 2017;69(2):277-290.

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