The ACR and NPF Guidelines for the treatment of PsA recommend anti-TNF therapy first-line for treatment naïve patients and second-line for patients with prior anti-TNF or prior anti-IL-12/23 experience.[2]

cimzia® (certolizumab pegol)

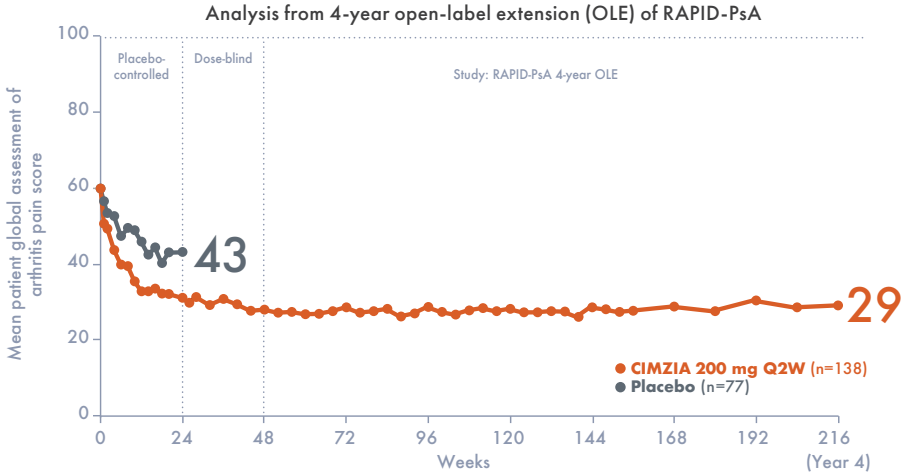
FOR THE TREATMENT OF ADULTS WITH MODERATE-TO-SEVERE PLAQUE PSORIASIS (PSO) WHO ARE CANDIDATES FOR SYSTEMIC THERAPY OR PHOTOTHERAPY, AND ADULTS WITH ACTIVE PSORIATIC ARTHRITIS (PsA)[1]

PsA

SUSTAINED PAIN REDUCTION THROUGH 4 YEARS

Change from baseline in patient's global assessment of arthritis pain through year 4[3-4*‡]

Analysis from 4-year open-label extension (OLE) of RAPID-PsA



*Pain assessment is a part of the ACR score. Pain assessment is done by the patient; hence, individual assessment/score may vary from patient to patient
†Patient assessment of arthritis pain, VAS: 0=no pain, 100=most severe pain
‡RS-NRI-LOCF: Randomized set. Nonresponder imputation. Last observation carried forward (LOCF)

ACR, American College of Rheumatology; Q2W, every 2 weeks; VAS; visual analog scale.

In psoriatic arthritis patients, the primary efficacy end point at Week 12 in RAPID-PsA was ACR20, with 58% of CIMZIA 200 mg Q2W patients achieving ACR20 at Week 12 vs 24% of placebo patients.[3]

SOME PsA PATIENTS ACHIEVED

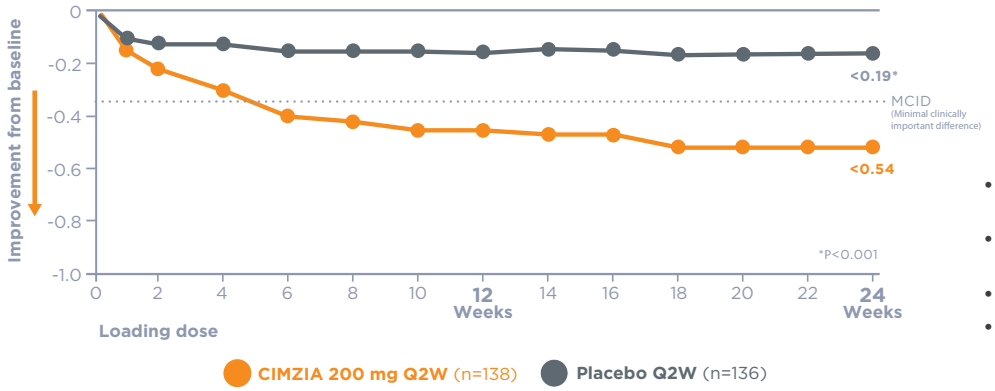
50%

REDUCTION IN PAIN
score in Year 4 CIMZIA 200 mg Q2W[3]

- Baseline pain score was 60 (VAS: 0=no pain and 100=most severe pain) for both the placebo arm and the CIMZIA 200 mg Q2W arm[5]
- Data were imputed using nonresponder imputation (NRI) for missing categorical data through Week 24 then last observation carried forward (LOCF) for Weeks 24 through 216
- **Limitations of OLE data**: Potential bias due to open-label treatment and lack of long-term placebo control beyond Week 24
- The results of this post hoc analysis should be interpreted with caution as the analysis was not prespecified in the original protocols

CLINICALLY SIGNIFICANT IMPROVEMENTS IN PHYSICAL FUNCTION

RAPID-PsA STUDY: Mean improvement from baseline in physical function (HAQ-DI)[4,6]



Q2W, every 2 weeks.

30%

3 OUT OF 10 PSORIASIS PATIENTS MAY DEVELOP PSORIATIC ARTHRITIS[7]
This makes treating both psoriasis and psoriatic arthritis all the more meaningful.

- Change from baseline in the Health Assessment Questionnaire-Disability Index (HAQ-DI) score was a prespecified secondary end point at Week 24[1]
- Baseline HAQ-DI score was 1.30 for the placebo arm and 1.33 for the CIMZIA 200 mg Q2W arm[4]
- MCID was defined as a reduction in HAQ-DI from baseline of ≥0.35
- Graph data represent randomized set and last observation carried forward (LOCF) for patients withdrawn for any reason, missing Week 24 measurement, or placebo patients who use escape treatment
- Physical function was a prespecified secondary end point.

Study Design
RAPID-PsA was a randomized, multicenter, phase 3 trial in patients with active PsA. The trial was double-blind and placebo-controlled through week 24, followed by an extension study that was dose-blind through week 48 and open-label through week 216. In this study, 409 patients who had failed ≥1 DMARDs (nonbiologic or biologic) were randomized (1:1:1) to CIMZIA 200 mg Q2W (n=138), CIMZIA 400 mg Q4W (n=135), or placebo (n=136). Patients were stratified by prior TNFi exposure; primary nonresponders were excluded.

IMPORTANT SAFETY INFORMATION

Serious and sometimes fatal side effects have been reported with CIMZIA, including tuberculosis (TB), bacterial sepsis, invasive fungal infections (such as histoplasmosis), and infections due to other opportunistic pathogens (such as Legionella or Listeria). Patients should be closely monitored for the signs and symptoms of infection during and after treatment with CIMZIA. Lymphoma and other malignancies, some fatal, have been reported in children and adolescent patients treated with TNF blockers, of which CIMZIA is a member. CIMZIA is not indicated for use in pediatric patients.

CIMZIA®
(certolizumab pegol)

Indications

- CIMZIA is indicated for the treatment of adults with moderate-to-severe plaque psoriasis who are candidates for systemic therapy or phototherapy.
- CIMZIA is indicated for the treatment of adults with active psoriatic arthritis.

Important Safety Information

CONTRAINDICATIONS

CIMZIA is contraindicated in patients with a history of hypersensitivity reaction to certolizumab pegol or to any of the excipients. Reactions have included angioedema, anaphylaxis, serum sickness, and urticaria.

SERIOUS INFECTIONS

Patients treated with CIMZIA are at increased risk for developing serious infections that may lead to hospitalization or death. Most patients who developed these infections were taking concomitant immunosuppressants such as methotrexate or corticosteroids.

Discontinue CIMZIA if a patient develops a serious infection or sepsis.

Reported infections include:

- **Active tuberculosis (TB), including reactivation of latent TB. Patients with TB have frequently presented with disseminated or extrapulmonary disease. Test patients for latent TB before CIMZIA use and during therapy. Initiate treatment for latent TB prior to CIMZIA use.**
- **Invasive fungal infections, including histoplasmosis, coccidioidomycosis, candidiasis, aspergillosis, blastomycosis, and pneumocystosis. Patients with histoplasmosis or other invasive fungal infections may present with disseminated, rather than localized, disease. Antigen and antibody testing for histoplasmosis may be negative in some patients with active infection. Consider empiric anti-fungal therapy in patients at risk for invasive fungal infections who develop severe systemic illness.**
- **Bacterial, viral, and other infections due to opportunistic pathogens, including Legionella and Listeria.**

Carefully consider the risks and benefits of treatment with CIMZIA prior to initiating therapy in the following patients: with chronic or recurrent infection; who have been exposed to TB; with a history of opportunistic infection; who resided in or traveled in regions where mycoses are endemic; with underlying conditions that may predispose them to infection. Monitor patients closely for the development of signs and symptoms of infection during and after treatment with CIMZIA, including the possible development of TB in patients who tested negative for latent TB infection prior to initiating therapy.

- Do not start CIMZIA during an active infection, including localized infections.
- Patients older than 65 years, patients with co-morbid conditions, and/or patients taking concomitant immunosuppressants may be at greater risk of infection.
- If an infection develops, monitor carefully and initiate appropriate therapy.

MALIGNANCY

Lymphoma and other malignancies, some fatal, have been reported in children and adolescent patients treated with TNF blockers, of which CIMZIA is a member. CIMZIA is not indicated for use in pediatric patients.

- Consider the risks and benefits of CIMZIA treatment prior to initiating or continuing therapy in a patient with known malignancy.
- In clinical trials, more cases of malignancies were observed among CIMZIA-treated patients compared to control patients.
- In CIMZIA clinical trials, there was an approximately 2-fold higher rate of lymphoma than expected in the general U.S. population. Patients with rheumatoid arthritis, particularly those with highly active disease, are at a higher risk of lymphoma than the general population.
- Malignancies, some fatal, have been reported among children, adolescents, and young adults being treated with TNF blockers. Approximately half of the cases were lymphoma, while the rest were other types of malignancies, including rare types associated with immunosuppression and malignancies not usually seen in this patient population
- Postmarketing cases of hepatosplenic T-cell lymphoma (HSTCL), a rare type of T-cell lymphoma, have been reported in patients treated with TNF blockers, including CIMZIA. These cases have had a very aggressive disease course and have been fatal. The majority of reported TNF blocker cases have occurred in patients with Crohn's disease or ulcerative colitis, and the majority were in adolescent and young adult males. Almost all of these patients had received treatment with azathioprine or 6-mercaptopurine concomitantly with a TNF blocker at or prior to diagnosis. Carefully assess the risks and benefits of treating with CIMZIA in these patient types.
- Cases of acute and chronic leukemia were reported with TNF blocker use.

HEART FAILURE

- Worsening and new onset congestive heart failure (CHF) have been reported with TNF blockers. Exercise caution and monitor carefully.

HYPERSENSITIVITY

- Angioedema, anaphylaxis, dyspnea, hypotension, rash, serum sickness, and urticaria have been reported following CIMZIA administration. If a serious allergic reaction occurs, stop CIMZIA and institute appropriate therapy. The needle shield inside the removable cap of the CIMZIA prefilled syringe contains a derivative of natural rubber latex which may cause an allergic reaction in individuals sensitive to latex.

HEPATITIS B VIRUS REACTIVATION

- Use of TNF blockers, including CIMZIA, may increase the risk of reactivation of hepatitis B virus (HBV) in patients who are chronic carriers. Some cases have been fatal.
- Test patients for HBV infection before initiating treatment with CIMZIA.
- Exercise caution in patients who are carriers of HBV and monitor them before and during CIMZIA treatment.
- Discontinue CIMZIA and begin antiviral therapy in patients who develop HBV reactivation. Exercise caution when resuming CIMZIA after HBV treatment.

NEUROLOGIC REACTIONS

- TNF blockers, including CIMZIA, have been associated with rare cases of new onset or exacerbation of central nervous system and peripheral demyelinating diseases, including multiple sclerosis, seizure disorder, optic neuritis, peripheral neuropathy, and Guillain-Barré syndrome.

HEMATOLOGIC REACTIONS

- Rare reports of pancytopenia, including aplastic anemia, have been reported with TNF blockers. Medically significant cytopenia has been infrequently reported with CIMZIA.
- Consider stopping CIMZIA if significant hematologic abnormalities occur.

DRUG INTERACTIONS

- Do not use CIMZIA in combination with other biological DMARDs.

AUTOIMMUNITY

- Treatment with CIMZIA may result in the formation of autoantibodies and, rarely, in development of a lupus-like syndrome. Discontinue treatment if symptoms of a lupus-like syndrome develop.

IMMUNIZATIONS

- Patients on CIMZIA should not receive live or live-attenuated vaccines.

ADVERSE REACTIONS

- The most common adverse reactions in CIMZIA clinical trials (≥8%) were upper respiratory infections (18%), rash (9%), and urinary tract infections (8%).

References: 1. CIMZIA [prescribing information]. Smyrna, GA: UCB, Inc. **2.** Singh JA, Guyatt G, Ogdie A, et al. Special article: 2018 American College of Rheumatology/National Psoriasis Foundation Guideline for the Treatment of Psoriatic Arthritis. *Arthritis Rheum*. 2019;71(1):5-32. **3.** van der Heijde D, Deodhar A, FitzGerald O, et al. 4-year results from the RAPID-PsA phase 3 randomised placebo-controlled trial of certolizumab pegol in psoriatic arthritis. *RMD Open*. 2018;4(1):e000582. **4.** Data on file. UCB, Inc.; Smyrna, GA. **5.** Mease PJ, Fleischmann R, Deodhar AA, et al. Effect of certolizumab pegol on signs and symptoms in patients with psoriatic arthritis: 24-week results of a Phase 3 double-blind randomised placebo-controlled study (RAPID-PsA). *Ann Rheum Dis*. 2014;73(1):48-55. **6.** Gladman D, Fleischmann R, Coteur G, Woltering F, Mease PJ. Effect of certolizumab pegol on multiple facets of psoriatic arthritis as reported by patients: 24-week patient-reported outcome results of a phase III, multicenter study. *Arthritis Care Res (Hoboken)*. 2014;66(7):1085-1092. **7.** Elmets CA, Leonardi CL, Davis DMR, et al. Joint AAD-NPF guidelines of care for the management and treatment of psoriasis with awareness and attention to comorbidities. *J Am Acad Dermatol*. 2019;80(4):1073-1113.

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Driven by **science.**

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