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)

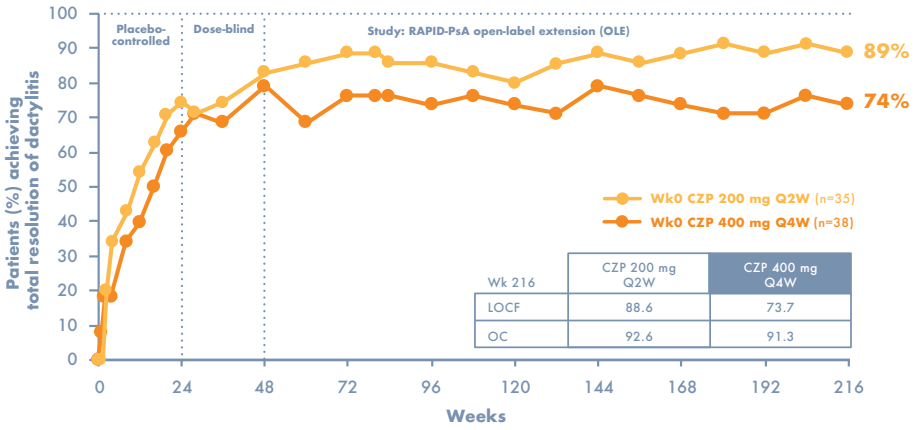
FOR THE TREATMENT OF ADULTS WITH MODERATE-TO-SEVERE PLAQUE PSORIASIS (PSO) WHO ARE CANDIDATES FOR SYSTEMIC THERAPY OR PHOTOTHERAPY, AND ADULTS WITH ACTIVE PSORIATIC ARTHRITIS (PsA)[1]

PsA

DEMONSTRATED IMPROVEMENT IN DACTYLITIS SUSTAINED AT WEEK 24

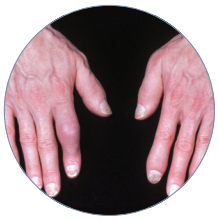
Total resolution of dactylitis over 216 weeks[3-4]

Post hoc analysis from 4-year open-label extension (OLE) of RAPID-PsA



Wk 216	CZP 200 mg Q2W	CZP 400 mg Q4W
LOCF	88.6	73.7
OC	92.6	91.3

Post hoc analysis: Total resolution defined as having at least 1 digit affected and with a difference in circumference ≥10% compared with the opposite digit (LDI >0), achieving complete clearance (LDI=0)



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

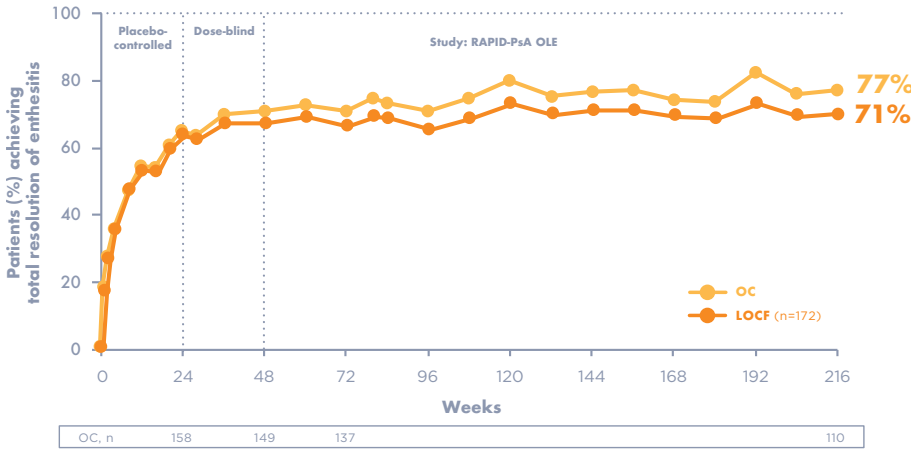
- **27% of CIMZIA patients and 26% of placebo patients** had dactylitis at baseline[2-3]
- Prespecified secondary end point was "Change from Baseline in the LDI at Weeks 12 and 24 (other timepoints were exploratory)"
- **Limitations of OLE data:** Potential bias due to open-label treatment and lack of long-term placebo control beyond Week 24
- **This subgroup analysis is a post hoc analysis.** The RAPID-PsA study was not powered for this subgroup analysis, nor was the analysis error controlled. Therefore, these results should be interpreted with caution, and the data observed in this subgroup cannot be regarded as statistically significant

CZP, certolizumab pegol; LDI, Leeds Dactylitis Index; Q2W, every 2 weeks; Q4W, every 4 weeks.

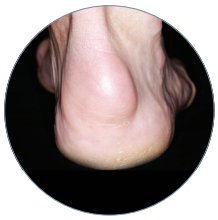
CONSISTENT IMPROVEMENT IN ENTHESITIS DEMONSTRATED OVER 4 YEARS

Total resolution of enthesitis in combined CIMZIA dose (OC and LOCF)[3-4]

Post hoc analysis from 4-year open-label extension (OLE) of RAPID-PsA



Post hoc analysis: Total resolution of enthesitis defined as the % of patients with baseline involvement (LEI >0) achieving complete clearance (LEI =0)



- **64% of CIMZIA patients and 67% of placebo patients** had enthesitis at baseline[3-5]
- Prespecified secondary end point was "Change from Baseline in the LEI at Weeks 12 and 24 (other time points were exploratory)"
- **Limitations of OLE data:** Potential bias due to open-label treatment and lack of long-term placebo control beyond Week 24
- **This subgroup analysis is a post hoc analysis.** The RAPID-PsA study was not powered for this subgroup analysis, nor was the analysis error controlled. Therefore, these results should be interpreted with caution, and the data observed in this subgroup cannot be regarded as statistically significant
- CIMZIA combined dose included patients receiving CIMZIA 200 mg Q2W and patients receiving CIMZIA 400 mg Q4W

LEI, Leeds Enthesitis Index; LOCF, last observation carried forward; OC, observed case; Q2W, every 2 weeks; Q4W, every 4 weeks.

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®
(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.

- 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 that 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

Avoid use of live vaccines during or immediately prior to initiating CIMZIA. Update immunizations in agreement with current immunization guidelines prior to initiating CIMZIA therapy.

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.

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Driven by **science.**

Please see the **Full Prescribing Information** provided by the UCB representative or visit **CIMZIAhcp.com**