

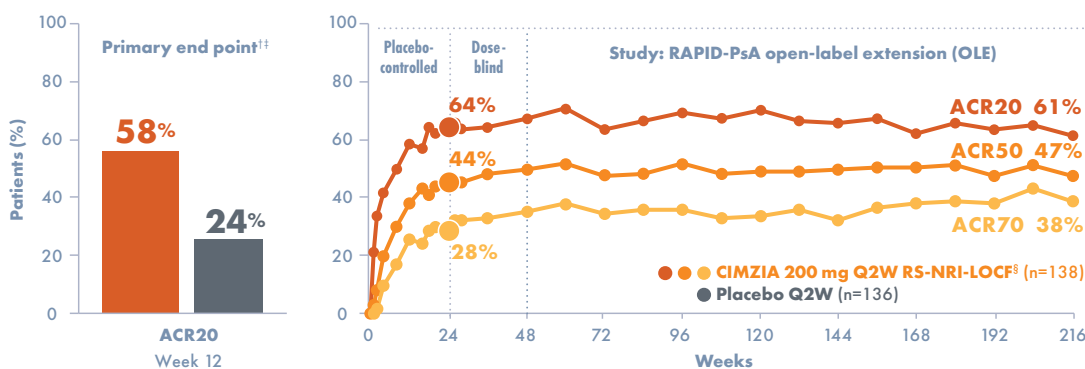
The ACR and NPF Guidelines for the treatment of PsA recommend anti-TNF therapy first-line for treatment naïve patients and second-line for patients with prior anti-TNF or prior anti-IL-12/23 experience.<sup>2</sup>



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)<sup>1</sup>

# RAPID IMPROVEMENT IN JOINT PAIN AND STIFFNESS, MAINTAINED THROUGH 4 YEARS

ACR20/50/70 response rates in CIMZIA 200 mg Q2W patients<sup>1,3-5††</sup>



Q2W, every 2 weeks.

- Placebo [n=136] rates at Week 24—ACR20: 24%; ACR50: 13%; ACR70: 4%.<sup>1,3</sup>
- Line graph to Week 216 represents patients who were randomized initially to CIMZIA 200 mg Q2W
- American College of Rheumatology (ACR) response criteria assess changes in swollen and tender joints, pain, functional ability, patient and physician global assessment, and acute-phase reactant. ACR20/50/70 relates to 20%-50%-70% response improvement
- **Limitations of OLE data:** Potential bias due to open-label treatment and no long-term placebo comparator for ACR responder rates beyond Week 24
- 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 OLE through Week 216<sup>3</sup>

\*The same patients may not have responded at each timepoint  
 †RS-NRI: Randomized set nonresponder imputation  
 ††P<0.001 vs placebo. Imputation is NRI for the primary end point  
 §RS-NRI-LOCF: Randomized set. Nonresponder imputation. Last observation carried forward (LOCF)  
 ||58% of CIMZIA 200 mg Q2W patients at 12 weeks vs. 24% of placebo patients; 21% and 33% of CIMZIA patients at 1 to 2 weeks vs 7% and 12% of placebo patients, respectively

## 8 OUT OF 10 PATIENTS ASSESSED RADIOGRAPHICALLY EXPERIENCED NO PROGRESSION OF JOINT DAMAGE OVER 4 YEARS



80% of radiographically assessed patients experienced no progression of joint damage over 4 years (CIMZIA 200 mg Q2W; n=98).<sup>3||</sup> The remainder experienced minimal progression.<sup>3</sup>

- The radiographic primary end point was mean change from baseline in mTSS at Week 24 (-0.02 with CIMZIA 200 mg Q2W [n=138] vs 0.18 with placebo [n=136]; P<0.05).<sup>3¶</sup>
- Patients treated with CIMZIA 400 mg Q4W did not demonstrate greater inhibition of radiographic progression compared with placebo-treated patients at Week 24<sup>1</sup>
- **Limitations of open-label extension (OLE) data:** Weeks 48 through 216 were an OLE phase of the study. As with any long-term, uncontrolled OLE, there were several limitations with this portion of the study. Limitations of OLE data include potential bias due to open-label treatment, lack of long-term control beyond Week 24, and the potential enrichment of the population with responders

||“No progression” was defined as a change from baseline in mTSS of ≤0.5. When “no progression” was defined as a change from baseline in mTSS of ≤0, 63.3% of x-rayed patients experienced no progression. Results are from observed case analysis<sup>3</sup>

¶Randomized set. For placebo patients who escaped early to CIMZIA, the Week 24 values were linearly extrapolated; ANCOVA model. For patients with two radiographs but a missing Week 24 or baseline film, linear extrapolation was performed in all approaches. Results are from observed case analysis<sup>3</sup>

mTSS, modified Total Sharp Score; Q2W, every 2 weeks; Q4W, every 4 weeks.

### 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.



## 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 ( $\geq 8\%$ ) 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.