BACKGROUND

Two populations from the RAPID 1 RCT were eligible to enter the OLE:

- Week 52 CZP Completers: all patients randomized to CZP who completed the 52-week RCT and were required to withdraw at Week 52 due to inefficacy or adverse events.
- CZP ITT population (N=783): all patients randomized to CZP in the feeder study; cDose Reduction Population is defined as all Week 52 CZP Completers who received CZP 400 mg Q2W + MTX for ≥6 months in the OLE and had their CZP dose reduced to 200 mg Q2W; dSafety Population is defined as all patients treated with ≥1 dose of CZP in RCT or OLE (event rate is calculated based on the CZP ITT population (Figure 2)).

CONCLUSIONS

- Rapid improvements in ACR responses in the RAPID 1 RCT and OLE were maintained over 5 years, with ≥90% of patients maintaining ≥20% improvement from Week 52 to Week 256.
- Serious infections/infestations were increased in the OLE compared with the RCT, with a higher incidence of viral infections.
- No new safety signals were observed in the OLE compared with the RCT.
- The efficacy and safety profile of CZP + MTX treatment was maintained over 5 years, providing long-term benefits for patients with RA.

References


Acknowledgments

THU0192/5-Year Results from the RAPID 1 Trial and Open-Label Extension: Long-Term Safety and Efficacy of Certolizumab Pegol in Combination with Methotrexate in the Treatment of Rheumatoid Arthritis
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