

May 12, 2022

Steven D. Pearson, MD, MSc
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Re: ICER's Assessment of Treatments for Lupus Nephritis: 12-month update

Dear Dr. Pearson,

GlaxoSmithKline (GSK) appreciates the opportunity to provide further evidence in response to the Institute for Clinical and Economic Review's (ICER) 12-month assessment update of the comparative clinical effectiveness and value of voclosporin and belimumab for the treatment of lupus nephritis (LN).

GSK would like to make stakeholders aware of the recent publication¹ of a post-hoc analysis of the Belimumab International Study in Lupus Nephritis (BLISS-LN), a Phase 3, multinational, double blind, 104-week trial in which 448 patients with LN were randomized to receive intravenous belimumab 10 mg/kg or placebo, each with standard therapy*.

- Rovin B, Furie R, Teng YKO, et al. A Secondary Analysis of the Belimumab International Study in Lupus Nephritis Trial Examined Effects of Belimumab on Kidney Outcomes and Preservation of Kidney Function in Patients with Lupus Nephritis. *Kidney Int.* 2022;101(2):403-413. DOI: <https://doi.org/10.1016/j.kint.2021.08.027>

Data from the post-hoc analysis was presented at the American College of Rheumatology Convergence 2020 and the abstract² was referenced in ICER's final report.

We would like to thank ICER for the opportunity to submit additional evidence.

Sincerely,



Stewart Wetmore, PharmD, MBA, BCPS
Sr Director, Specialty/ Immunology, US Value, Evidence and Outcomes.

* Standard therapy (ST) was defined as Mycophenolate mofetil (MMF) + high-dose steroids, followed by MMF + low-dose steroids or cyclophosphamide + high-dose steroids, followed by azathioprine + low-dose steroids

References

1. Rovin B, Furie R, Teng YKO, et al. A Secondary Analysis of the Belimumab International Study in Lupus Nephritis Trial Examined Effects of Belimumab on Kidney Outcomes and Preservation of Kidney Function in Patients with Lupus Nephritis. *Kidney Int.* 2022;101(2):403-413. DOI: <https://doi.org/10.1016/j.kint.2021.08.027>
2. Furie R, Rovin B, Houssiau F, et al. Effects of Belimumab on Renal Outcomes, Overall SLE Control and Biomarkers: Findings from a Phase 3, Randomized, Placebo-controlled 104-week Study in Patients with Active Lupus Nephritis [abstract]. *Arthritis Rheumatol.* 2020; 72 (suppl 10).
<https://acrabstracts.org/abstract/effects-of-belimumab-on-renal-outcomes-overall-sle-control-and-biomarkers-findings-from-a-phase-3-randomized-placebo-controlled-104-week-study-in-patients-with-active-lupus-nephritis/>