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Long-Term Remission of Proteinuria in Primary Membranous Nephropathy After Four Doses of Budoprutug, a Novel Anti-CD19 Monoclonal Antibody

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Background

Primary membranous nephropathy (PMN) is an autoimmune-mediated disease caused by circulating autoantibodies. Achieving complete remission (CR) of proteinuria (UPCR ≤0.3 g/g) is a key treatment goal. While anti-CD20 monoclonal antibodies (mAbs) are effective, most patients do not reach CR. CD19 is a promising target due to its broader expression on B cells, including plasmablasts and plasma cells. In a Phase 1b study, budoprutug (100 or 200 mg IV) was administered in two initial doses followed by two additional doses six months later. By Week 48, 3 patients achieved CR and 2 achieved partial remission (Cortazar et al, ASN 2024). Here we report the long-term outcomes up to 3 years post initial treatment in 4 of these patients.

Methods

Patients were enrolled in the clinical trial (NCT04652570) between December 2021 and December 2022. Budoprutug was given IV on Days 1 and 15, with 3/4 patients receiving two additional doses six months later. Patients were followed through Week 48 or 72 in the trial and up to 3 years after initial dosing.

Results

All patients had proteinuria at Baseline (UPCR 3.1 to 6.6 g/g). Patient 1 achieved CR during the study and remains in remission after 3 years (UPCR 0.2 g/g) without further immunosuppression. Patient 2 achieved serologic remission and PR (UPCR 0.33 g/g) during the

study, relapsed ~1 year post-treatment, and received two doses of rituximab 1,000 mg. Six months later, UPCR was 0.6 g/g. Patient 3 received only the two initial doses of budoprutug and remains in CR at 30 months (UPCR 0.26 g/g) without additional immunosuppression. Patient 4 achieved CR during the study and remains in remission 28 months post initial study treatment (UPCR 0.2 g/g). Patients tolerated budoprotug well, with no treatment-related grade 3 or higher adverse events, and no reported adverse effects after the study period.

Conclusion

In four patients with PMN we followed long-term at our clinics, prior study treatment with four doses of the novel anti-CD19 mAb budoprutug led to long-term control of proteinuria for up to 3 years, 3/4 received no additional immunosuppressive treatment and no clinically significant treatment-related AEs were observed. These findings support further investigation of budoprutug as a potential disease-modifying therapy for PMN.

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