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UPDATED INTERIM RESULTS OF A PHASE 1/2 STUDY OF BION-1301 IN PATIENTS WITH IGA NEPHROPATHY

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Objectives: Immunoglobulin A nephropathy (IgAN) is the leading cause of primary glomerulonephritis and has limited treatment options, especially for high-risk patients. A proliferation-inducing ligand (APRIL), a TNF superfamily cytokine, is elevated in patients with IgAN and promotes the production of pathogenic galactose-deficient IgA1 (Gd-IgA1), leading to immune complex deposition and kidney injury. BION-1301 is a novel humanized monoclonal antibody that blocks APRIL, representing a potential disease-modifying approach to target the pathogenesis of IgAN. Here we present updated interim results of BION-1301 treatment in patients with IgAN.

Methods: In Part 3 of the phase 1/2 open-label, multicohort trial ADU-CL-19 (NCT03945318), key eligibility criteria include adults with biopsy-proven IgAN within 10 years, eGFR ≥30 mL/min/1.73m^2, urine protein excretion ≥0.5 g/24 hours or UPCR ≥0.5 g/g, and stable/optimized dose of RASi (or intolerant). Cohort 1 (n=10) receives 450 mg of BION-1301 administered IV every 2 weeks, transitioning to SC at 600 mg every 2 weeks after at least 24 weeks. Cohort 2 (up to 30 patients) receives 600 mg of BION-1301 SC every 2 weeks.

Results: In both cohorts, BION-1301 was generally well-tolerated, with no SAEs or terminations due to AEs as of last observation (13 October 2022). Trough concentrations of BION-1301 following 600 mg SC Q2W (Cohort 2) are consistent with those following 450 mg IV Q2W (Cohort 1). Following both IV and SC dosing, BION-1301 produced rapid and sustained reductions in IgA and Gd-IgA1. In Cohort 1, sustained, clinically meaningful reductions in proteinuria were seen by 12 weeks and were sustained through 52 weeks (Figure). Reduction in UPCR in Cohort 2 through 24 weeks were consistent with those observed in Cohort 1.

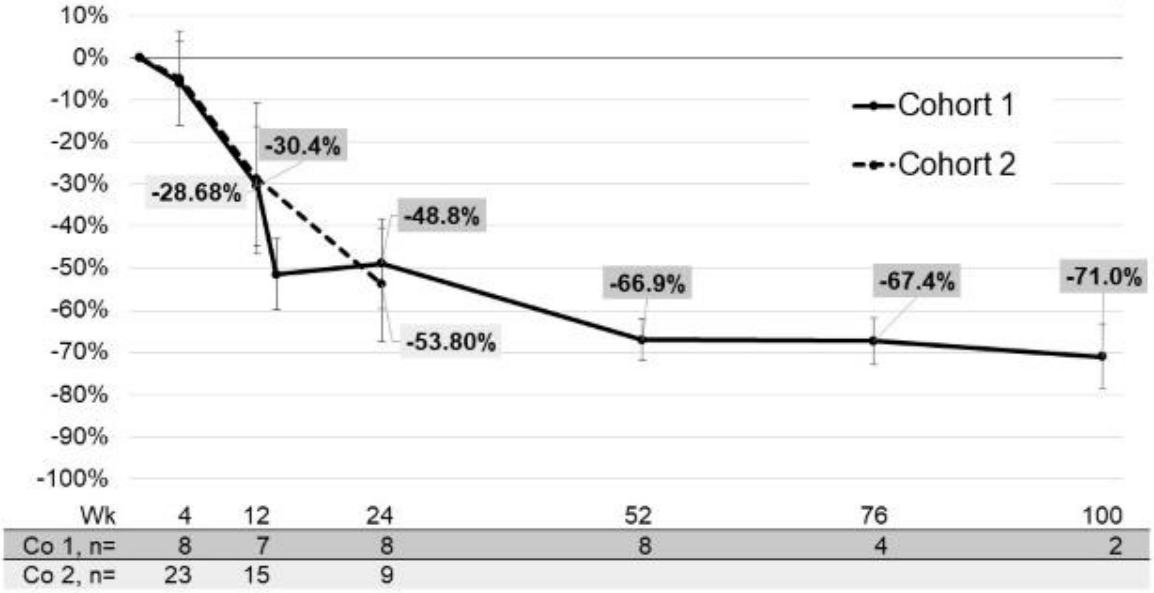
Conclusions: BION-1301 offers disease-modifying potential depleting pathogenic Gd-IgA1 and reducing proteinuria in patients with IgAN who remain at risk for progression with residual proteinuria despite optimized standard-of-care treatment.

Figure. Percent reduction in UPCR with BION-1301 in patients with IgAN

UPCR

% Reduction
(Geometric Mean ± SE)

Data cut-off Oct. 13, 2022



Wk	4	12	24	52	76	100
Co 1, n=	8	7	8	8	4	2
Co 2, n=	23	15	9			

Median (range) baseline protein excretion: Cohort 1, 1.2 (0.7, 6.5) g/day ; Cohort 2, 1.0 (0.6, 2.7) g/day