end-stage-kidney-disease (ESKD). The target of therapy is complete response (proteinuria <0.5-0.7gr/24h with [near-]normal glomerular filtration rate) by 12 months, but this can be extended in patients with baseline nephrotic-range proteinuria. Hydroxychloroquine is recommended with regular ophthalmological monitoring. In active proliferative LN, initial (induction) treatment with mycophenolate mofetil (MMF 2-3g/day, or mycophenolic acid at equivalent dose) or low-dose intravenous cyclophosphamide (CY; 500mg x6 biweekly doses), both combined with glucocorticoids (pulses of intravenous methylprednisolone, then oral prednisone 0.3-0.5mg/kg/day) is recommended. MMF/CNI (especially tacrolimus) combination and high-dose CY are alternatives, for patients with nephrotic-range proteinuria and adverse prognostic factors. Subsequent long-term maintenance treatment with MMF or azathioprine should follow, with no or low-dose (<7.5 mg/day) glucocorticoids. The choice of agent depends on the initial regimen and plans for pregnancy. In non-responding disease, switch of induction regimens or rituximab are recommended. In pure membranous LN with nephrotic-range proteinuria or proteinuria >1g/24h despite renin-angiotensin-aldosterone blockade, MMF in combination with glucocorticoids is preferred. Assessment for kidney and extra-renal disease activity, and management of comorbidities is lifelong with repeat kidney biopsy in cases of incomplete response or nephritic flares. In ESKD, transplantation is the preferred kidney replacement option with immunosuppression guided by transplant protocols and/or extra-renal manifestations.

Conclusion: The updated recommendations intend to inform rheumatologists, nephrologists, patients, national professional societies, hospital officials, social security agencies and regulators about the treatment of LN based on most recent evidence.

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BLISS-LN: A RANDOMISED, DOUBLE-BLIND, PLACEBO-CONTROLLED PHASE 3 TRIAL OF INTRAVENOUS BELIMUMAB IN PATIENTS WITH ACTIVE LUPUS NEPHRITIS

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Background: Lupus nephritis (LN), a serious manifestation of systemic lupus erythematosus (SLE), affects nearly 70% of patients (pts) in high-risk groups. To preserve renal function, LN requires fast and effective treatment. Despite medical advances, progression rates at 15 years to end-stage renal disease (ESRD) remain >40% for pts with diffuse proliferative LN. Belimumab (BEL), approved in pts aged ≥5 years with active SLE, improved renal parameters in pts with baseline renal involvement in a *post hoc* analysis of Phase 3 trials data.

Objectives: To assess efficacy and safety of intravenous (IV) BEL vs placebo (PBO), plus standard therapy (ST), in pts with active LN.

Methods: BLISS-LN is a Phase 3, randomised, double-blind, PBO-controlled, 104-week study (GSK Study BEL114054, NCT01639339). Adults with SLE and biopsy-proven LN (class III, IV, and/or V) were randomised (1:1) to monthly BEL 10 mg/kg IV or PBO, plus ST. Primary endpoint: Primary Efficacy Renal Response (PERR); defined as urine protein creatinine ratio [uPCR] ≤0.7; estimated glomerular filtration rate [eGFR] within 20% of the pre-flare value or ≥60 ml/min/1.73m^2; no rescue therapy) at Week (Wk) 104. Key secondary endpoints: Complete Renal Response (CRR; defined as uPCR <0.5; eGFR within 10% of the pre-flare value or ≥90 ml/min/1.73m^2; no rescue therapy) at Wk 104; PERR at Wk 52; time to renal-related event (defined as ESRD/doubling of serum creatinine/renal worsening/renal disease-related treatment failure) or death. Other endpoints: time to PERR/CRR sustained through Wk 104; SLEDAI-S2K score <4 points at Wk 104; safety.

Results: Overall, 448 pts were randomised (efficacy: 223/group; safety: 224/group). Significantly more BEL (43%) than PBO (32.3%) pts achieved PERR at Wk 104 (OR 1.55, 95% CI 1.04, 2.32; p=0.0311). More BEL than PBO pts achieved key secondary and other efficacy endpoints (Table).

Overall, 214 (95.5%) BEL and 211 (94.2%) PBO pts had ≥1 adverse event (AE); 58 (25.9%) BEL and 67 (29.9%) PBO pts had ≥1 serious AE; 29 (12.9%) pts in each group had ≥1 AE resulting in study treatment discontinuation; 4 (1.8%) BEL and 3 (1.3%) PBO pts developed on-treatment fatal AEs.

Conclusion: In the largest LN study to date, data from BLISS-LN demonstrate that BEL plus ST significantly improves LN renal responses compared with ST alone with a favourable safety profile.

Study funding: GSK.

Table.

Endpoint, n (%)	PBO (n=223)	BEL (n=223)	OR/HR (95% CI) vs PBO	p-value
CRR at Wk 104*	44 (19.7)	67 (30.0)	OR 1.74 (1.11, 2.74)	0.0167
PERR at Wk 52*	79 (35.4)	104 (46.6)	OR 1.59 (1.06, 2.38)	0.0245
Time to PERR through Wk 104†	72 (32.3)	96 (43.0)	HR 1.46 (1.07, 1.98)	0.0157
Time to CRR through Wk 104†	44 (19.7)	67 (30.0)	HR 1.58 (1.08, 2.31)	0.0189
Time to renal-related event or death†	63 (28.3)	35 (15.7)	HR 0.51 (0.34, 0.77)	0.0014
SLEDAI-S2K score <4 points at Wk 104*	41 (18.4)	62 (27.8)	OR 1.76 (1.11, 2.78)	0.0164

*PBO and BEL columns represent the n (%) responders

†Data presented as n (cumulative incidence)

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