

Abstract 90 Table 1

		Week 12		Week 28	
		Treatment group			
		PBO	DZP	PBO	DZP
BICLA	N	7	11	6	10
	Responders, n (%)	1 (14.3)	5 (45.5)	1 (16.7)	3 (30.0)
	Non-responders, n (%)	6 (85.7)	6 (54.5)	5 (83.3)	7 (70.0)
SRI-4	N	7	12	6	11
	Responders, n (%)	1 (14.3)	5 (41.7)	1 (16.7)	4 (36.4)
	Non-responders, n (%)	6 (85.7)	7 (58.3)	5 (83.3)	7 (63.6)

BICLA, British Isles Lupus Assessment Group (BILAG)-based Composite Lupus Assessment; DZP, dapirolizumab pegol; PBO, placebo; SRI-4, Systemic Lupus Erythematosus Responder Index-4

systemic lupus erythematosus (SLE). We report data from a Phase I double-blind, multiple dose study (NCT01764594) of dapirolizumab pegol (DZP), a PEGylated anti-CD40L Fab' fragment, in SLE patients.

Methods Twenty-four SLE patients were randomised (2:1, stratified by the presence of anti-phospholipid antibodies) to receive DZP (loading dose 30 mg/kg, then 15 mg/kg every 2 weeks for 10 weeks) or placebo. Patients were followed for 18 weeks. Objectives: safety and tolerability of DZP (primary); disease activity measures (BICLA and SRI-4; exploratory). Genes expressed by plasma cells, B cells, other immune cells and transcripts associated with SLE disease activity were analysed by qPCR.

Results No serious adverse events (AEs), thromboembolic events or deaths occurred. Most treatment-emergent AEs (TEAEs) were mild or moderate, transient, and resolved without intervention. Nasopharyngitis was the most common TEAE (6 patients in the DZP group; none with placebo). One patient withdrew due to upper respiratory tract infection (DZP group). Of DZP-treated patients evaluable for BICLA and SRI-4, 46% and 42% respectively, responded by Week 12 (vs 14% placebo; Table 1). Rapid and maintained mechanism-related gene expression changes were observed, particularly in plasma cell genes (IgA, IgG, IgJ) from the DZP group.

Conclusions DZP was well tolerated and demonstrated improvement in clinical measures of disease activity. A Phase II study is evaluating efficacy and safety of DZP in SLE patients (NCT02804763).

Background and aims The purpose of this study is to use *in silico* molecular docking and *in vivo* study to identify the potential of *Bryophyllum pinnatum* as B cell depleting and immune suppression agent in SLE.

Methods *In silico* was done by docking 32 phytochemical compounds well known immunosuppressive herbs into three B cell activating receptors: B cell activating factor receptors (BAFF-R), trans- membrane activator and calcium modulator and cyclophilin ligand interactor (TACI), and B-cell maturation antigen (BCMA). *In vivo* study was done in pristane induced mice model treated with different doses of *Bryophyllum pinnatum* extract (B1 :10.5 mg/kgBW/day, B2 :21 mg/kgBW/day, and B3 :42 mg/kgBW/day). Extracts were given everyday per orally from 3rd to 4th months after pristane injection. spleen mature B cell (CD19⁺ CD22⁺), Th1, Th2 and Th17 percentages were assessed using flow cytometry assay and serum anti-dsDNA level using ELISA.

Results It was revealed that one compound from *Bryophyllum pinnatum* had the strongest binding affinity to BAFF-R (−6.3 kcal/mol), to TACI (four compounds, −6.4 kcal/mol) and to BCMA (−7 kcal/mol). *In vivo* study revealed that *Bryophyllum pinnatum* treatment significantly lower the percentages of CD19⁺ CD22⁺ cell and anti-dsDNA levels in dose dependent manner which significantly lower compared to control (p=0.002 and p=0.036 respectively). *Bryophyllum pinnatum* treatment lowered also Th1, Th2, and Th17 percentages dose dependently compared to control.

Conclusions *Bryophyllum pinnatum* is a potential natural product which may be used for B cell depleting agent in SLE treatment by suppressing Th1, Th2 and Th17 percentages.

91 POTENTIAL NOVEL NATURAL B CELL DEPLETING AND IMMUNOSUPPRESSION AGENT IN LUPUS TREATMENT USING BRYOPHYLLUM PINNATUM. IN SILICO AND IN PRISTANE INDUCED LUPUS MICE

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92 EFFECT OF CURCUMIN AND VITAMIN D ON DISEASE ACTIVITY, FATIGUE, AND CYTOKINE PROFILE IN SYSTEMIC LUPUS ERYTHEMATOSUS PATIENTS WITH DEFICIENCY VITAMIN D

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