

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<sup>+</sup> CD22<sup>+</sup>), 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<sup>+</sup> CD22<sup>+</sup> 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**

<sup>1</sup>U Kalsum\*, <sup>1</sup>N Nurdiana, <sup>2</sup>MZ Pratama, <sup>3</sup>H Kalim, <sup>1</sup>K Handono. <sup>1</sup>Medical Faculty Brawijaya University, Clinical Pharmacology, Malang, Indonesia; <sup>2</sup>Medical Faculty Brawijaya University, Internal Medicine, Malang, Indonesia; <sup>3</sup>Medical Faculty Brawijaya University, Rheumato-Immunology, Malang, Indonesia

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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**

CS Wahono\*, H Kalim, I Saveria, CD Setyorini, Z Wahyuni, RA Dimpudus, H Kusworini. Medical Faculty Brawijaya University, Rheumato-Immunology, Malang, Indonesia

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