

Supplemental Material

METHODS

Exclusion criteria

Exclusion criteria included severe, active lupus nephritis (as assessed by the investigator or urine protein/creatinine ratio of >200 mg/mmol or estimated creatinine clearance <30 mL/min); severe, active central nervous system (CNS) or peripheral neurologic disease; use of oral prednisone >40 mg/day (or equivalent); change in antimalarial or immunosuppressant dose within 30 days of baseline; initiation of immunosuppressants within 90 days of baseline; intravenous immunoglobulin treatment within 180 days of baseline; previous treatment with any B-cell targeted therapies; or previous treatment with any biologic therapy within 90 days or 5 half-lives of baseline. Recipients of plasmapheresis or a live vaccine within 90 days of baseline and patients with any infection or serious infection within 30 days of screening or 90 days of baseline, respectively, or who had a recent surgery, malignancy, or any condition or event that, in the investigator's opinion, would pose an unacceptable risk to the patient were excluded. Patients with active hepatitis B, hepatitis C, human immunodeficiency virus (HIV) or evidence of untreated active or untreated latent tuberculosis and women who were pregnant or breastfeeding were also excluded.

Pharmacodynamic and safety assessments

Blood samples were collected for determination of serum tabalumab concentrations and changes in total B cells, B-cell subsets, mean B-cell activating factor (BAFF) levels, and immunoglobulins were measured. B cells were assessed by flow cytometry. Total BAFF (membrane and soluble) was assessed by validated ELISA assay that did not differentiate between free and tabalumab-bound BAFF. Safety assessments were conducted at every visit; these included all adverse events (AEs), serious AEs (SAEs), treatment-emergent AEs (TEAEs), adverse events of special interest, the Columbia-Suicide Severity Rating Scale (C-SSRS), vital signs, and clinical laboratory data. AEs of special interest included infection, major adverse cardiovascular events (MACE), malignancies, injection-site reactions, allergic/hypersensitivity reactions, and depression-associated events. Serious infections were defined as events resulting in hospitalization, a congenital anomaly, or death, or an event that is persistently incapacitating, life threatening, or significant for any other reason. Severe infections were rated as such by investigators on a mild,

moderate, or severe scale. MACE events were adjudicated in a blinded manner by an external committee to ensure all events were judged uniformly by the same group using the same definition. The Quick Inventory of Depressive Symptomatology (QIDS-SR16) was assessed every 6 months. Anti-drug antibodies (ADAs) were assessed approximately every 3 months.