

Title	Disease	Drug Name	Drug Involvement	Important inclusions	Important exclusions
Pilot Trial of Belimumab in Early Lupus	SLE (newly diagnosed)	Belimumab	B lymphocyte stimulator (BLyS/BAFF)-specific inhibitor that blocks the binding of soluble BLyS/BAFF, a B cell survival factor, to its receptors on B cells.	<ol style="list-style-type: none"> 1) ACR SLE diagnosed within 2 years. 2) Concomitant treatment with hydroxychloroquine unless documented inability to tolerate. 3) Diagnosis of SLE per current ACR classification criteria (at least 4 of 11 criteria). 4) 2) SLEDAI-2K ≥ 4 	<ol style="list-style-type: none"> 1) Previous exposure to disease modifying drugs such as azathioprine, mycophenolate mofetil, cyclophosphamide, or cyclosporine. 2) Previous exposure to biologic therapies including rituximab, belimumab or other agents that have been investigated for SLE.
A Phase III, Randomized, Double-Blind, Placebo-Controlled, Multicenter Study to Evaluate the Efficacy and Safety of Obinutuzumab in Patients with ISN/RPS 2003 Class III or IV Lupus Nephritis	LN (Class III or IV)	Obinutuzumab	Recombinant, monoclonal, humanized, and glycoengineered type II CD20 antibody of the IgG1 isotype that specifically targets the extracellular loop of the CD20 transmembrane antigen that is expressed on the surface of non-malignant and malignant pre-B and mature B lymphocytes but not on hematopoietic stem cells, pro-B cells, normal plasma cells, or other normal tissue	<ol style="list-style-type: none"> 1) UPCR ≥ 1 on a 24-hour collection at screening. 2) Active or active/chronic ISN/RPS 2003 Class III or IV proliferative LN by renal biopsy performed in the 6 months prior to screening or during screening. <ul style="list-style-type: none"> -One or more active glomerular lesions must be present. -Class V disease may be present in addition to Class III or IV. 3) Receipt of at least one dose of pulse methylprednisolone IV (≥ 250 mg) or equivalent for treatment of the current episode of active LN during the 6 months prior to screening or during screening, or to be given on Day 1 prior to the first infusion. 	<ol style="list-style-type: none"> 1) Receipt of any of the following excluded therapies: <ul style="list-style-type: none"> - Any anti-CD20 therapy less than 9 months prior to screening. - Cyclophosphamide, tacrolimus, ciclosporin, or voclosporin during the 2 months prior to screening. - Any biologic therapy (other than anti-CD20) such as, but not limited to, belimumab, ustekinumab, anifrolumab, secukinumab, or atacicept during the 2 months prior to screening or during screening - Oral inhibitors of Janus-associated kinase (JAK), Bruton's tyrosine kinase (BTK), or tyrosine kinase 2 (TYK2), including baricitinib, tofacitinib, upadacitinib, filgotinib, ibrutinib, or fenebrutinib or any investigational agent during the 2 months prior to screening or during screening.

<p>A randomized, double-blind, placebo-controlled study of ALPN-101 in systemic lupus erythematosus (SLE)</p>	<p>SLE</p>	<p>ICOS-L vIgD-Fc (ALPN-101)</p>	<p>Fc fusion protein of a human inducible T cell costimulator ligand (ICOS-L) variant Ig domain (vIgD™) designed to inhibit simultaneously the CD28 and ICOS inflammation pathways.</p>	<ol style="list-style-type: none"> 1) SLEDAI-2K 30 score of ≥ 6 (excluding lupus headache and/or organic brain syndrome), and must have a clinical score at Baseline (i.e., Day 1 prior to randomization) of ≥ 4 (excluding lupus headache and/or organic brain syndrome). 2) Women with intact uterus: PAP smear with HPV status ≤ 12 months prior to Baseline (Day 1). 3) Subject must have met the 2019 European League Against Rheumatism (EULAR) / American College of Rheumatology (ACR) Classification Criteria for SLE (73), including at least one clinical criterion and an additive criterion score of ≥ 10 at any time in the past up to and including the day of Screening. 4) Subjects must have SLEDAI-2K 30 clinical points in at least one of the following at Screening and Baseline: arthritis; myositis; urinary casts; hematuria; proteinuria; pyuria; rash; alopecia; mucosal ulcers; pleurisy; pericarditis. 	<ol style="list-style-type: none"> 1) Proteinuria consistent with nephrotic syndrome (i.e., ≥ 3.5 grams proteinuria/day, estimated based on UPCr ≥ 350 mg/mmol) at Screening.
<p>(Active within this month) A Phase 2, Randomized, Double-blind, Placebo-controlled, Dose-finding Study to Evaluate the Efficacy and Safety of ALXN2050 in Adult Participants with Proliferative Lupus Nephritis (LN) or Immunoglobulin A Nephropathy (IgAN)</p>	<p>LN (Class III or IV)</p>	<p>FD inhibitor (ALXN2050)</p>	<p>An orally active, small molecule, complement FD inhibitor that is in development for the treatment of complement-mediated diseases. ALXN2050 acts by binding reversibly to FD, blocking its serine protease activity and thereby inhibiting AP activation and the resulting production of C3 cleavage fragments, anaphylatoxins of complement components 3a and 5a (C3a and C5a), and downstream MAC complex.</p>	<ol style="list-style-type: none"> 1) Vaccinated against meningococcal infection (Neisseria meningitidis) within 3 years prior to, or at the time of randomization. Participants who initiate study intervention < 2 weeks after receiving a meningococcal vaccine must receive appropriate prophylactic antibiotics until at least 2 weeks after the vaccination. Please refer patient to PCP for vaccination prior to referral to study. 2) Proteinuria with UPCr ≥ 1 g/g based on one 24-hour urine collection during the Screening Period. 	<ol style="list-style-type: none"> 1) History of N. meningitidis infection.

<p>A two-year, phase III randomized, double-blind, parallel-group, placebo-controlled trial to evaluate the safety, efficacy, and tolerability of 300 mg subcutaneous secukinumab versus placebo, in combination with Standard of Care therapy, in patients with active lupus nephritis</p>	<p>SLE</p>	<p>Secukinumab</p>	<p>A recombinant, high-affinity fully human monoclonal anti-human IL-17A antibody of the IgG1/kappa isotype.</p>	<ol style="list-style-type: none"> 1) SLE with documented history of at least 4 of the 11 criteria for SLE as defined by the American College of Rheumatology (ACR), or LN as the sole clinical criterion in the presence of ANA or anti-dsDNA antibodies. 2) UPCR ≥ 1 at Screening. 3) Active urinary sediment (presence of cellular casts (granular or red blood cell casts) or hematuria (>5 red blood cells per high power field). 4) Subjects must be currently on, or willing to initiate SoC induction therapy for LN according to the institutional practices using MPA or low-dose CYC in addition to corticosteroids. 	<ol style="list-style-type: none"> 1) Receipt of more than 3000 mg i.v. pulse methylprednisolone (cumulative dose) within the 12 weeks prior to Baseline.
<p>A Phase 2, Multicenter, Randomized, Double-Blind, Placebo-Controlled, Parallel-Group Study to Evaluate Efficacy, Safety, and Tolerability of MT-7117 in Subjects with Diffuse Cutaneous Systemic Sclerosis</p>	<p>dcSSc</p>	<p>Dersimelagon</p>	<p>An orally-administered, small molecule, which acts as an agonist of melanocortin-1 receptor (MC1R) to reduce active inflammatory and fibrotic processes in adults with diffuse cutaneous systemic sclerosis (dcSSc).</p>	<ol style="list-style-type: none"> 1) Disease duration ≤ 5 years from the first non-Raynaud's phenomenon manifestation. 2) Has diffuse cutaneous form of SSc according to Leroy and Medsger's criteria 3) Has an mRSS of 15 to 45 units at screening and have clinical skin involvement proximal and distal to the elbows, knees, or both or any truncal involvement, with or without face involvement. 	<ol style="list-style-type: none"> 1) Treatment of SSc disease with: <ol style="list-style-type: none"> a. Cyclophosphamide, rituximab, or cyclosporine received within 26 weeks prior to screening. b. Small molecules such as JAK inhibitors (e.g., tofacitinib) received within 12 weeks prior to screening. c. Pirfenidone received within 12 weeks prior to screening. d. Infliximab, certolizumab, golimumab, adalimumab, abatacept, tocilizumab within 10 weeks prior to screening. e. Etanercept within 4 weeks prior to screening. f. Oral, intravenous, or intramuscular corticosteroids (prednisone > 10 mg/day or equivalent) received within 30 days prior to screening. g. Nintedanib within 12 weeks prior to screening. h. More than 1 of the immunosuppressant therapy listed below as concomitant therapy with study drug, has changed one of the medications below within 12 weeks prior to screening, or not on a stable dose of the same medication for at least 12 weeks prior to screening. <ol style="list-style-type: none"> i. Mycophenolate (up to 3 g/day), or ii. Mycophenolic acid (up to 2.14 g/day), or iii. Methotrexate (up to 25 mg/Week), or

<p>(2-week screen window!) A multicenter, randomized, double-blind, placebo-controlled, parallel-group study to evaluate the efficacy and safety of dapirolizumab pegol in study participants with moderately to severely active systemic lupus erythematosus</p>	<p>SLE</p>	<p>Dapirolizumab</p>	<p>Antigen-binding fragment (Fab') of an antibody conjugated to polyethylene glycol (PEG) with specificity for CD40 ligand (CD40L) and is being developed for SLE. Evidence suggests that CD40L plays a key role in regulating T cell, B cell, and antigen-presenting cell activity, and considerable pharmacological evidence suggests that its blockade is efficacious in inflammatory and autoimmune conditions.</p>	<p>1) Subjects must meet the EULAR/ACR criteria and also have several positive lupus serologies.</p>	
<p>A Phase 1b, Multiple Ascending-dose Study of EQ001 in Subjects with Systemic Lupus Erythematosus with or without Active Proliferative Lupus Nephritis</p>	<p>LN (Class III or IV)</p>	<p>Itolizumab</p>	<p>Humanized recombinant immunoglobulin G1 (IgG1) monoclonal antibody (mAb) that selectively targets the extracellular scavenger receptor cysteine-rich (Sc) membrane-distal domain 1 of human CD6, a co-stimulatory membrane glycoprotein associated with T cell modulation and implicated in several autoimmune and inflammatory diseases, including psoriasis, multiple sclerosis, rheumatoid arthritis, and Sjögren's disease.</p>	<p>1) All subjects must be on MMF/MPA 2 to 3 g/day. Requires induction treatment due to newly diagnosed LN or relapsing/flaring disease. Subjects need to be on MMF/MPA (2 to 3 g/day) and pulse systemic corticosteroids as part of their induction treatment. The MMF/MPA and pulse systemic corticosteroids can be started within 12 weeks prior to Day 1 or on Day 1.</p> <p>2) Has a urine protein to creatinine ratio of > 1000 mg/g based on the mean of two 24-hour urine collections or a single urine protein to creatinine ratio of > 2000 mg/g based on a single 24-hour urine collection. The 2 collections must be within 12 weeks from Day 1 with 1 collected and resulted within 6 weeks of Day 1.</p> <p>3) Subjects that require induction treatment must receive at least 2 consecutive days of pulse systemic corticosteroids of methylprednisolone (≥500 mg) or equivalent and be able to receive it 12 weeks prior to Day 1 or start on Days 1 and 2; all induction</p>	<p>1) History of cancer with signs of disease within the 5 years prior to Screening.</p>

				subjects must be able to undergo a taper of systemic corticosteroids during the first 10 weeks of treatment.	
(Biweekly visits with 4 abdominal injections each visit) A Phase 2b Dose Ranging Study to Evaluate the Efficacy and Safety of Rozibafusp Alfa (AMG 570) in Subjects With Active Systemic Lupus Erythematosus (SLE) With Inadequate Response to Standard of Care (SOC) Therapy	SLE	AMG 570	A bispecific IgG2 antibody inhibiting both ICOSL and BAFF.	<p>1) Hybrid SLEDAI score \geq 6 points with a "Clinical" hSLEDAI score \geq 4 points.</p> <p>2) Must be taking at least 1 but no more than 2 of the following SLE treatments unless there is a documented intolerance to the following treatments: anti-malarial (hydroxychloroquine, chloroquine, or quinacrine), azathioprine, methotrexate, mycophenolate mofetil/acid mycophenolic, or dapsone. Treatment should be taken for \geq 12 weeks prior to screening and must be a stable dose for \geq 8 weeks prior to screening. If subject is taking 2 of the above mentioned SLE treatments, 1 of these must be either hydroxychloroquine, quinacrine, or chloroquine.</p>	1) Urine protein creatinine ratio \geq 3000 mg/g (or equivalent) at screening or induction therapy for lupus nephritis within 1 year prior to screening visit.