 **SCLERODERMA PROGRAM**

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| **STUDY**  | **DESCRIPTION** | **CONTACT/PI** |
| **SKIN** |
| **ACT14604** | **Efficacy and safety of SAR156597 in the treatment of diffuse cutaneous Systemic Sclerosis (dcSSc): A randomized, double-blind, placebo-controlled, 24-week, proof of concept study*** 24-week Double Blind/ 11 week follow up
* 94 subjects
* Some low dose background therapies are allowed (methotrexate < 15 mg, mycophenolate <2 g)
* Weekly SAR156597/placebo 200 mg sub cutaneous injections.
* Disease duration: <36 and mRSS >10 and < than 35 at screening
* Currently approving visiting nurses for injections to limit travel time.8 onsite visits and 4 phone calls (on-site injections add additional injection only visits)
* FVC < and DLCO corrected for hemoglobin <40%
 |  **RecruitingMonica Sanborn**734-232-2090monsan@med.umich.edu**PI: Dr. Young** |
| **GSK2330811** | **A multi-centre, randomized, double-blind (sponsor open), placebo-controlled, repeat-dose, proof of mechanism study to evaluate the safety, tolerability, pharmacokinetics, pharmacodynamics and explore efficacy of GSK2330811 in participants with diffuse cutaneous systemic sclerosis.*** 12 week Double Blind/ 16 week follow up
* 20-40 subjects across two cohorts
* Some background therapies including mycophenolate (3 grams/stable dose last 3 months) and low dose oral corticosteroids (<10 mg stable 1 month) are allowed.
* Bi- weekly 100/300 mg of GSK2330811 or placebo sub cutaneous injections. Totaling 6 injections of the course of the study.
* Disease duration: <60 and mRSS >10 and < than 35 at screening plus additional active disease criteria: increasing skin involvement in the last 6 months, disease duration of <18 months or CRP of >6 mg/l)
* FVC <50% of predicted or DLCO corrected <40% of predicted are exclusionary.
* Optional blister biopsy
 | **Recruiting April 2018Monica Sanborn**734-232-2090monsan@med.umich.edu**PI: Dr. Nagaraja** |
| **TOFA-SSc** | **Evaluation of tofacitinib in early diffuse cutaneous systemic sclerosis (dcSSc): A phase I/II two center safety and tolerability study** * 24- week Double Blind/ 24 weeks of open label extension
* 15 subjects across two centers
* Some background therapies including mycophenolate (2 grams/1-month stable prior to baseline; methotrexate <25mg) and low dose oral corticosteroids (stable <10mg) are allowed.
* Daily tofacitinib/placebo, 5mg, oral tablets BID
* Disease duration: <60 and mRSS > 10 and <45
* Must have had Zostavax or be willing to obtain following protocol guidelines during screening.
* FVC <50% of predicted or DLCO corrected <40% of predicted are exclusionary.
* 4 visits + 1 phone during DB portion and 3 visits plus 2 phone calls for open label extension.
* Biopsies at two time points
 | **RecruitingMonica Sanborn**734-232-2090monsan@med.umich.edu**PI: Dr. Khanna** |
| **BRAVOS** | **Evaluation of Brentuximab Vedotin for Diffuse Cutaneous Systemic Sclerosis: A Phase ½ Multicenter Randomized, Double Blinded, Safety Study*** Three ascending dose cohorts will receive brentuximab/placebo (0.6mg/kg, 1.2mg/kg and 1.8mg/kg. Each cohort will receive intravenous administration every 3 weeks for 21 weeks, with a total of 8 doses. 24 participants with 8 in each cohort.
* Double blind treatment for 21 weeks followed by 27 weeks of follow up.
* Disease duration: <60 and mRSS > 10 and <45 at screening plus additional active disease criteria: increasing skin involvement in the last 6 months or an mRSS that has not decreased >3 units within last 6 months or meets protocol specific criteria around SSc lung disease.
* Documentation of at least 12 weeks of ongoing immunosuppressive therapy for SSc at time of enrollment with 4 weeks of stable dose for: methotrexate <25mg, mycophenolate <3g, or Azathioprine <3mg/kg/day.
* FVC <60% of predicted or DLCO corrected <60% of predicted are exclusionary
* Skin biopsies at two time points.
 | **RecruitingMonica Sanborn**734-232-2090monsan@med.umich.edu**PI: Dr. Khanna** |
| **JBT-101** | **A Multi-Center, Randomized, Double-Blind, Placebo-Controlled Phase III Trial to Evaluate Efficacy and Safety of Lenabasum in Diffuse Cutaneous Systemic Sclerosis*** Double blind treatment for 21 weeks followed by optional open label extension
* 11 visits four to six weeks a part
* 3 cohorts: 5mg, 20mg and placebo capsules with 1:1:1 randomization.
* Disease duration: < 6 years from the first non-Raynaud’s. If duration is >3 years and less than 6, then mRSS must be > 15.
* Overlap disease is allowed if SSc is the dominant clinical disease
* Immunosuppressive therapy allowed, new or increased doses of medication should not occur within 8 weeks prior to screening.
* Skin biopsies at two time points.
 | **Recruiting March 2018Erica Bush**734-936-5615ebush@med.umich.edu**PI: Dr. Nagaraja** |
| **DIGITAL ULCERS** |
| **RESCUE** | **Pilot study to assess the efficacy and safety of riociguat vs. placebo in scleroderma –associated digital ulcers*** 16 week double blind (8 week titration/8 week dose maintenance
* 16 week Open Label
* 20 subject, 5 centers
* TID dosing of riociguat/placebo titrated up beginning with 1mg to 2.5 mg (0.5 is also available should tolerance be an issue)
* Diagnosis of SSc and one visible, active, ischemic DU at baseline located at or distal to the proximal interphalangeal joint, and that developed or worsened within 8 weeks prior to screening.
 | **RecruitingErica Bush**734-936-5615ebush@med.umich.edu**PI: Dr. Nagaraja** |
| **LUNG FIBROSIS** |
| **SLS 3** | **Combining the anti‐fibrotic effects of pirfenidone (PFD) with mycophenolate (MMF) for treating scleroderma‐ related interstitial lung disease.*** 18- month double blind, phase 2 with 1 month follow up visit
* 150 subjects
* Mycophenolate 250mg capsules + Pirfenidone 267mg capsules or placebo. The dosage will escalate if tolerated over a monthly 4 step titration plan.
* FVC‐% of <80% at screening and Grade >2 on the Magnitude of Task component of the Mahler Modified Dyspnea Index are inclusionary.
* FVS-% of 45% at screening or baseline; FEV1/FVC ration <0.68 at screening or baseline and DLCO corrected -% of 30% are all exclusionary.
* Disease duration of <84 months
* Extensive prohibited medication list with wash-out of at least 30 days, refer to protocol.
 | **Recruiting:Monica Sanborn**734-232-2090monsan@med.umich.edu**Dr. Nagaraja** |
| **JOINT CONTRACTURES** |
| **REACH** | **Novel Rehabilitation Strategies to improve are function in patients with Scleroderma*** Have a diagnosis of systemic sclerosis, diffuse cutaneous subset; disease duration < 5 years from 1st non Raynaud phenomenon sign or symptom
* Have a contracture of the hand and other joint in at least one arm, such as wrist, elbow, or shoulder, with the ability to demonstrate active range of motion in that arm
* Willing to travel to participate in therapy and outcome assessments.
* Have an Android, iPhone, iPad or computer tablet to load the home exercise App
 | **Coming SoonJennifer Serrano**734-232-2090monsan@med.umich.edu**Dr. Khanna/Dr. Murphy** |