mediated by the CB1 receptor indicated by an increased cell viability and reduction of caspase activity after combined treatment with CBD and CB1 antagonist AM251. Since CBD induced Erk1/2 phosphorylation seems to be independent of CB1 signalling, the involvement of other signalling pathways and/or a crosstalk with other Ca^{2+} channels or receptors seems likely and will be the focus of further investigations.

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OP0325

SAFETY AND EFFICACY OF LENABASUM IN AN OPEN-LABEL EXTENSION OF A PHASE 2 STUDY IN DIFFUSE CUTANEOUS SYSTEMIC SCLEROSIS SUBJECTS (DCSSC)

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Background: Lenabasum is a synthetic, non-immunosuppressive, selective cannabinoid receptor type 2 agonist that activates resolution of innate immune responses and limits fibrosis in animal models of SSc. Lenabasum had acceptable safety and tolerability, and improved efficacy outcomes in the 16-week, double-blinded, randomized, placebo-controlled Part A of Phase 2 trial JBT101-SSc-001 (NCT02465437) in dcSSc subjects.

Objectives: To provide long-term open-label safety and efficacy data in dcSSc subjects in study JBT101-SSc-001.

Methods: Subjects who completed Part A were eligible to receive oral lenabasum 20 mg BID in an open-label extension (OLE) that assessed safety and efficacy at 4 weeks, then every 8 weeks.

Results: 36/38 (95%) eligible subjects enrolled in the OLE, with mean interval of 134 (range 33-392) days or 19.1 weeks from end of dosing in Part A to start of OLE when subjects received only standard-of care drugs. 34/36 (94%) subjects were on stable doses of immunosuppressive drugs. At safety data cut-off, 31 (86%) subjects finished 1 year, 30 (83%) finished 18 months, and 24 finished ≥ 2 years in the OLE. Thirty-five (97%) subjects experienced at least 1 AE; 239 AEs have occurred during the OLE to date. Seven (19%) subjects had ≥ 1 AE considered related to lenabasum in the OLE. Only fatigue (1 subject) was considered definitely-related, none of the related AEs were serious or severe. Most subjects experienced AEs that were mild (n = 6, 17%) to moderate (n = 24, 67%) in maximum severity. Four (11%) had severe AEs and 1 (3%) had a life-threatening AE of renal crisis caused by high-dose steroids. AEs in $\geq 10\%$ of subjects: upper respiratory tract infection (n = 11, 31%), skin ulcer and arthralgia (each n = 6, 17%), urinary tract infection (n = 5, 14%), and diarrhea, nasopharyngitis, and cough (each n = 4, 11%). Dizziness and fatigue occurred in 3 (8.3%) subjects each.

At the time of efficacy data cut-off, 30/36 (83%) subjects had completed ≥ 18 months in the OLE. Improvement was seen in multiple physician- and patient-reported efficacy outcomes; selected outcomes are shown in **Figure 1**. Compared to Baseline at study start, the CRIS median score (primary efficacy outcome) was 0.99 (0.43 IQR) at Week 76 and mRSS declined by mean (SD) = -10.7 (7.2) points. HAQ-DI, Physician Global Assessment, Patient Global Assessment, skin symptoms, itch, and multiple PROMIS-29 domains also improved. FVC% predicted was relatively stable during the OLE; mean (SD) FVC% predicted decreased by 2.5% from study start.

Figure 1. Change from Baseline in Selected Efficacy Outcomes in OLE of Phase 2 Trial JBT101-SSc-001

Conclusion: Lenabasum continues to have a favorable safety and tolerability profile in the OLE of Phase 2 trial JBT101-SSc-001 with no lenabasum-related serious AEs or study discontinuations. Only 7 (19%) subjects had an AE related to lenabasum in ≥ 18 months of OLE dosing. ACR CRIS score, mRSS, Physician Global Assessment, and multiple patient-reported outcomes show continued improvement, although background therapy, potential for spontaneous improvement, and open-label dosing limit what can be definitely attributed to lenabasum.

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Reproductive issues in rheumatology

OP0326

DEVELOPMENT OF A STANDARDIZED MINIMAL CORE DATA SET FOR PREGNANCY REGISTERS IN RHEUMATOLOGY – RESULTS OF A EULAR TASK FORCE

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Background: Results from individual data collections on drug safety during pregnancy and outcomes of pregnancy in patients with inflammatory rheumatic diseases (IRD) are often limited due to small number of cases. Joint data analyses from different data sources could solve this problem.

Objectives: The aim of this EULAR task force was to define a core data set to facilitate joint analysis of pregnancy registers in rheumatology.

Methods: Scope and core areas of the core data set have been developed according to COS-STAD recommendations¹ by consensus. An initial list of data items possibly relevant for pregnancy registers was generated based on (I) a systematic literature search, (II) data items already collected by European pregnancy registers and (III) a survey amongst patient representatives. Consensus about the importance of each data item to be included in a core data set was reached by applying a 2-round Delphi survey where each item was rated on a numeric scale (1-3 = low importance, 4-6 = important but not critical, 7-9 = critical importance). Any data item that was considered as 'critical important' by at least 70% of responders in Delphi round 2 was included in the core set. During a face-to-face meeting of the EULAR task force, the inclusion or exclusion of data items with no consensus was finally decided.

Results: The scope was defined as follows: 'To develop a standardized core data set for data collection in prospective observational research and clinical care of pregnant women with IRD including the neonatal phase. All interventions the women receive will be covered. Patients should be enrolled at the earliest possible moment during pregnancy, and data should ideally be collected once every trimester. An additional visit should capture the neonatal phase'. Three core areas were described: 'Maternal information' (including demographics, IRD disease characteristics and comorbidities), 'Pregnancy' (including prior and current pregnancy(ies), delivery and neonatal outcomes) and 'Treatment' (including medication of IRD and other health conditions).

64 experts from 14 different European countries participated in the 2 rounds of Delphi (68% female; 84% physicians, 5% obstetricians, 5% epidemiologists, 3% patients, 3% midwives). Of the 148 data items, 85 were included in the final core set. The figure shows included items within the core areas.

Suggestion of items for a core data set for pregnancy registers in rheumatology		
MATERNAL INFORMATION	PREGNANCY	TREATMENT
Demographics Maternal age at conception Maternal body weight and height Maternal educational level and professional training Smoking and alcohol consumption during pregnancy	Prior pregnancy(ies) Number of prior pregnancy(ies) and parity Prior pre-eclampsia, eclampsia or HELLP syndrome Number of prior pregnancy losses (including spontaneous abortion, fetal death and stillbirths) Prior (preterm) delivery Congenital malformations of prior born infant(s)	Treatment 12 months prior to conception DMARD use Oral glucocorticoid use Use of potentially teratogenic medication
IRD disease characteristics Diagnosis Fulfillment of classification criteria Disease duration Prior important IRD manifestations ^a Physician reported disease severity Disease activity estimated with appropriate metric ^b Physician reported disease activity Flares during pregnancy Patient reported disease activity Patient reported global health Disease-specific auto-antibodies and activity markers ^c	Current pregnancy Planned pregnancy Use of assisted reproduction Estimated date of conception Indication of singleton or multiple pregnancy Comorbidities: arterial hypertension, gestational diabetes and thrombotic events Pre-eclampsia, eclampsia or HELLP syndrome Intrauterine growth restriction	Treatment of IRD during pregnancy DMARD use with name, dose and application interval, start and stop dates and reasons for stopping Oral glucocorticoid use with dose and application interval, start and stop dates Intravenous glucocorticoid use with application date NSAID use with application date
Concomitant diseases and adverse events Selected comorbidities: rheumatoid arthritis, systemic sclerosis, Sjögren's syndrome, Diabetes mellitus, hypertension, Heart disease, thrombotic events Maternal serious adverse events ^a Maternal death with date and cause of death	Delivery/Outcome Live birth Effective termination with reasons and WGA Perinatal loss with WGA Gestational age at birth Mode of delivery Placental/premature rupture of membranes Neonatal outcome Birth weight Gender Breastfeeding Congenital malformations, congenital heart block Chromosome abnormalities Hospital admission Neonatal death	Treatment of other health conditions during pregnancy Use of folic acid, antithrombotic drugs, aspirin, heparin or other anticoagulants

Abbreviations: DMARDs, disease-modifying antirheumatic drugs; HELLP, hemolysis, elevated liver enzymes and low platelets; NSAIDs, non-steroidal anti-inflammatory drugs; pre-, previous; WGA, whole-genome amplification.

^aThe EULAR task force will find additional consensus on disease specific auto-antibodies and markers including activity, level of severity or information of the disease in a consensus conference in 2020.

Conclusion: The consensus process resulted in an extensive list of data items recommended by experts to be collected as a minimum by pregnancy registers in rheumatology. This core data set applies to all pregnant women irrespective of the

underlying IRD. The EULAR task force plans to find consensus on additional disease specific advice.

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The future of therapeutic strategies

OP0327

FECAL MICROBIOTA TRANSPLANTATION IN SYSTEMIC SCLEROSIS: A DOUBLE-BLIND, PLACEBO-CONTROLLED RANDOMIZED PILOT TRIAL

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Background: Systemic sclerosis (SSc) is a progressive, multi organ, autoimmune disease marked by frequent and severe gastrointestinal (GI) afflictions and gut dysbiosis.

Objectives: Determine the safety and efficacy of fecal microbiota transplantation (FMT) using commercially-available anaerobic cultivated human intestinal microbiota (ACHIM) in patients with SSc.

Methods: The trial was a single-center, randomized, double-blind, placebo-controlled 16-week pilot of FMT by gastroduodenoscopy of ACHIM in SSc conducted at Oslo University Hospital. Primary endpoints were safety and clinical efficacy on GI symptoms assessed at weeks 4 and 16. Safety was assessed by observation, interviews and standardized safety form. Efficacy on GI symptoms was measured using the UCLA GIT 2.0 score questionnaire. Patients were defined as responders if reported symptom improvement was equivalent to the UCLA GIT definition of "minimally clinically important difference". Secondary and explorative endpoints included changes in relative abundance of total, immunoglobulin (Ig)A- and IgM-coated fecal bacteria measured by 16s rRNA sequencing; changes in modified Rodnan skin score, lung function, CRP, ESR, and patient and physician global. Descriptive statistics were applied for clinical endpoints and linear mixed models for microbial analysis.

Results: Ten patients with limited cutaneous SSc randomized to ACHIM (n=5) or placebo (n=5) were included. All patients were female with clinical apparent GI symptoms, mean age of 62 years and mean time from diagnosis of 12 yrs. Two placebo controls experienced procedure-related serious adverse events; one developed laryngospasms at first gastroduodenoscopy necessitating study exclusion, one duodenal perforation at final gastroduodenoscopy. Improvement in total GIT score was reported by 3/5 FMT patients compared to 2/4 placebo controls at weeks 4 and 16 (Figure 1). FMT effects were most pronounced on lower GI symptoms, with improvement reported by 5/5 FMT patients with diarrhea, distention/bloating and/or fecal incontinence at baseline compared to 2/4 placebo controls (Figure). Clinical secondary endpoints showed no differences and other side effects (stomach discomfort, bloating and diarrhea) were mild and transient. Fecal microbiota diversity (observed number of operational taxonomic units) was increased after FMT compared to placebo treatment at week 16 (p<0.006). Moreover, abundant bacterial genera in ACHIM were present within the total, and IgA- and IgM-coated fecal bacteria at both week 4 and 16 in the FMT group (Figure 2) but not in the placebo controls.