immunosuppressive drugs. At the time of data cut-off, all subjects who entered OLE completed 12 months of dosing. Nineteen/20 (95%) of subjects experienced at least 1 AE, with 59 AEs occurring among the subjects during the OLE to date. The majority of AEs were mild ($n = 16$, 80%), with 1 severe AE (fatigue) considered unrelated to lenabasum reported. AEs occurring in ≥ 2 subjects were: dermatomyositis worsening, dizziness, fatigue, herpes zoster, nasopharyngitis, nausea, upper respiratory tract infection, and urinary tract infection. No serious AEs related to lenabasum have been reported. Improvement was seen in multiple physician- and patient-reported efficacy outcomes; selected outcomes are presented in Figure 1. Mean (SE) changes from study start at Week 52 in the OLE were: CDASI activity score = -17.6 (SD), Patient Skin Activity VAS = -2.6 (SD); Skindex-29 Symptoms Domain = -21.6 (SD); Patient Itch VAS = -2.8 (SD); Physician Overall Disease VAS = -3.0 (SD); and Patient Pain VAS = -2.3 (SD). Improvements were seen in other efficacy outcomes. 12 subjects had no changes in immunosuppressive drugs during the OLE, 3 reduced chronic steroids, 2 reduced mycophenolate, 3 were switched from methotrexate to mycophenolate, 1 started methotrexate, and 1 had a burst and taper of steroids.

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

Conclusion: Lenabasum continues to have a favorable safety and tolerability profile in the OLE of the Phase 2 trial JBT101-DM-001 with no serious AEs or study discontinuations related to lenabasum. The CDASI activity score and multiple other physician and patient-reported outcomes improved, although limitations of attributing efficacy to lenabasum in the setting of open-label dosing is acknowledged. These data support further testing of lenabasum for the treatment of DM, and a Phase 3 study of lenabasum in DM has started.

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OP0242

SAFETY PROFILE OF NINTEDANIB IN PATIENTS WITH SYSTEMIC SCLEROSIS-ASSOCIATED INTERSTITIAL LUNG DISEASE AND IDIOPATHIC PULMONARY FIBROSIS

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Background: Nintedanib has been investigated in patients with systemic sclerosis-associated interstitial lung disease (SSc-ILD) in the SENSICIS trial and idiopathic pulmonary fibrosis (IPF) in the INPULSIS trials. These patient populations differ in age, sex, disease characteristics and comorbidities.

Objectives: To compare the safety and tolerability of nintedanib in patients with SSc-ILD and IPF.

Methods: Adverse events that occurred over 52 weeks of treatment in the SENSICIS and INPULSIS trials were assessed descriptively in subjects who received ≥ 1 dose of trial drug.

Results: A total of 576 subjects were treated in the SENSICIS trial (288 nintedanib; 288 placebo) and 1061 in the INPULSIS trials (638 nintedanib; 423 placebo). At baseline, mean (SD) age was 54.0 (12.2) and 66.8 (8.0) years in SENSICIS and INPULSIS, respectively. The proportion of males was 24.8% and 79.3%, respectively. Over 52 weeks, 19.4% and 10.8% of patients treated with nintedanib and placebo discontinued treatment in SENSICIS, compared with 24.5% and 18.9% of patients treated with nintedanib and placebo in INPULSIS. Gastrointestinal adverse events were the most frequently reported adverse events with nintedanib and, as expected based on the underlying disease, were more frequent in patients with SSc-ILD than IPF in both treatment groups (Table). Diarrhoea adverse events were reported in 75.7% and 31.6% of patients treated with nintedanib and placebo in SENSICIS, and 62.4% and 18.4% of patients treated with nintedanib and placebo in INPULSIS, respectively.

	SENSICIS		INPULSIS	
	Nintedanib (n=288)	Placebo (n=288)	Nintedanib (n=638)	Placebo (n=423)
Diarrhoea	218 (75.7)	91 (31.6)	398 (62.4)	78 (18.4)
Nausea	91 (31.6)	39 (13.5)	156 (24.5)	29 (6.8)
Vomiting	71 (24.7)	30 (10.4)	74 (11.6)	11 (2.6)
Nasopharyngitis	36 (12.5)	49 (17.0)	67 (10.5)	58 (13.7)
Cough	34 (11.8)	52 (18.1)	85 (13.3)	57 (13.5)
Upper respiratory tract infection	34 (11.8)	52 (18.1)	85 (13.3)	57 (13.5)
Decreased appetite	27 (9.4)	12 (4.2)	68 (10.7)	24 (5.7)
Upper respiratory tract infection	25 (8.7)	25 (8.7)	68 (10.7)	42 (9.9)
Abdominal pain	20 (7.0)	21 (7.3)	68 (10.7)	10 (2.4)
Pharyngitis	15 (5.2)	24 (8.3)	67 (10.5)	45 (10.6)
Congestive heart failure	31 (10.8)	20 (7.0)	40 (6.3)	33 (7.8)
Progression of IPF*	21 (7.3)	20 (7.0)	48 (7.5)	48 (11.3)
Death	10 (3.5)	10 (3.5)	10 (1.6)	0

Data shown are n (%) of patients with ≥ 1 such event. *Adverse events are listed by preferred term in the Medical Dictionary for Regulatory Activities (MedDRA). *Corresponds to MedDRA term "interstitial disease worsening and acute exacerbation".

Conclusion: The safety and tolerability profile of nintedanib in patients with SSc-ILD is similar to that observed in patients with IPF.

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OP0243

EFFICACY OF PIRFENIDONE IN SYSTEMIC SCLEROSIS RELATED INTERSTITIAL LUNG DISEASE – A RANDOMISED CONTROLLED TRIAL

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Background: Interstitial lung disease (ILD) is a major cause of morbidity and mortality in systemic sclerosis (SSc). (1) Lung fibrosis in systemic sclerosis shares