Long-term Safety and Efficacy of Lenabasum during 3 Years in an Open-Label Extension (OLE) of a Phase 2 Study of Lenabasum in Refractory Skin Disease in Dermatomyositis (DM)

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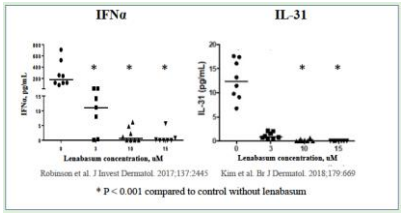
Background

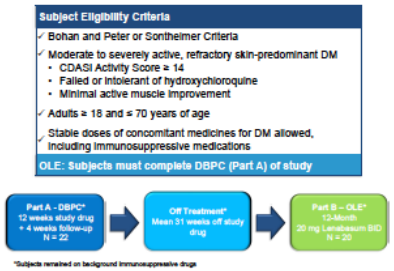
- Dermatomyositis (DM) is a serious multi-system autoimmune disease characterized in part by chronic activation of the innate immune system
- Current therapies for DM are frequently ineffective and include immunosuppressive drugs
- Lenabasum activates resolution in a human model of innate immune responses and reduces inflammation and fibrosis in multiple animal models
- Lenabasum inhibits IFNα, IL-1β, TNFα, and IL-31 production by DM PBMC.



Objective

- Evaluate the long-term safety and efficacy of lenabasum in people with DM who completed a Phase 2 randomized controlled trial

Methods

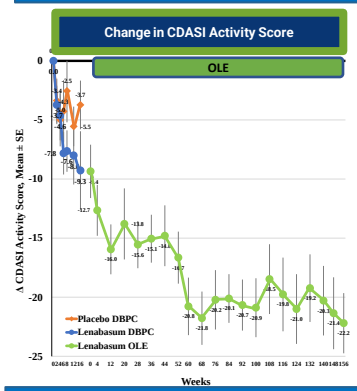


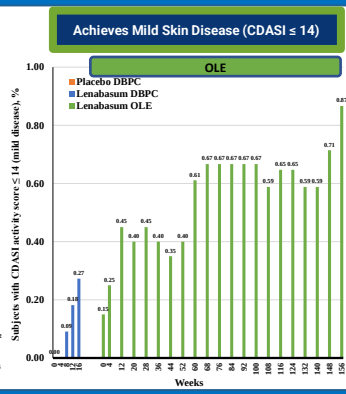
Baseline Characteristics

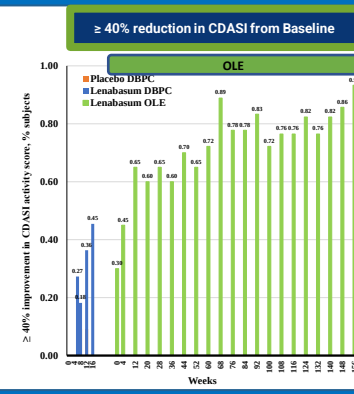
	OLE N = 20
Female, %	95.0%
Age, mean (SD)	52.1 (9.89)
White, %	95.0%
Immunosuppressive drugs, n, %	17 (85.0)
Physician CDASI activity score, 0 -100, mean (SD)	34.4 (9.03)
Patient skin global assessment (PtGA), 1-10, mean (SD)	5.5 (2.62)
Patient Itch, VAS 1-10, mean (SD)	5.5 (3.25)
Patient SKINdex-29 symptom score, 0-100, mean (SD)	58.6 (22.42)
Patient SKINdex-29 functioning score, 0-100, mean (SD)	28.1 (21.89)

✧At entry, most subjects had severely active and symptomatic skin disease despite current immunosuppressive therapy

Effects on Skin Disease

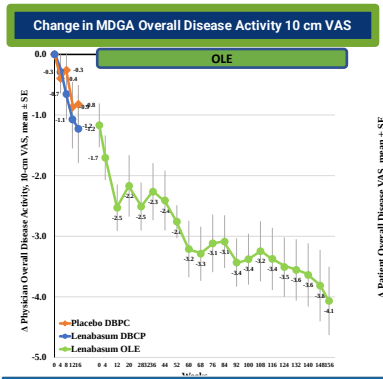


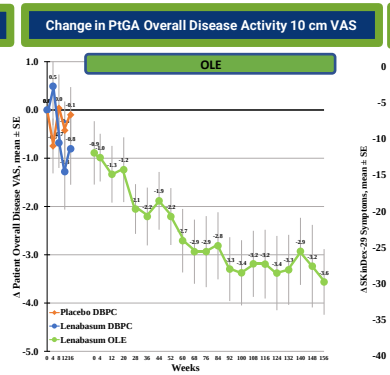


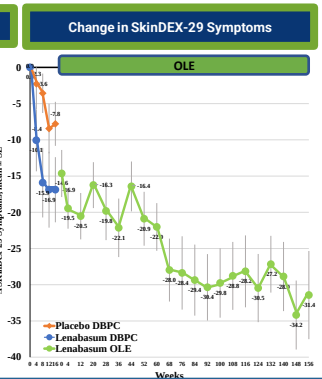


- **Medically meaningful and durable improvement in CDASI activity score was observed, with mean improvement in CDASI > 20 points from baseline at most visits starting at 1 year in OLE**
- **No subject had mild skin disease activity at baseline. 60-70% of subjects achieved mild skin disease activity after 1 year in OLE, with durable responses**
- **~75% of subjects achieved ≥ 40% reduction in CDASI activity score, a level that is associated with improvement in PRO**

Effects on Overall Disease and Quality of Life

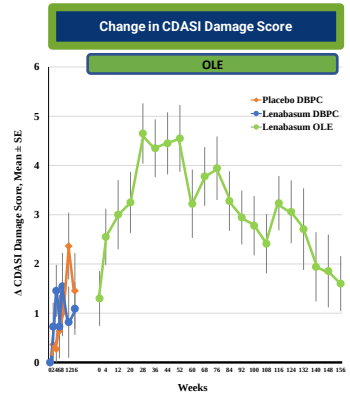


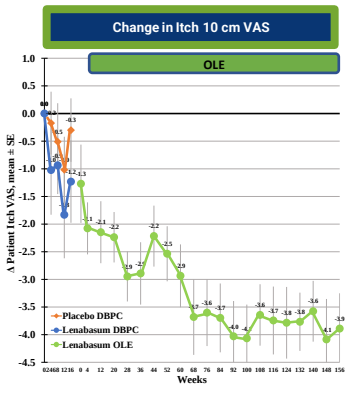


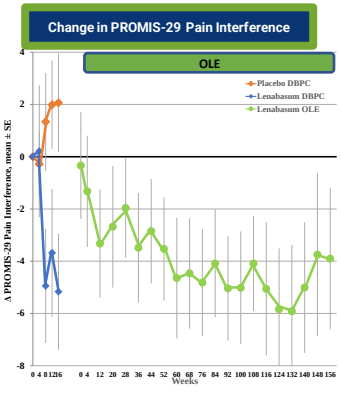


- **Overall disease activity, as assessed by both the patient and physician, improved during the OLE, through about 12-18 months, then remained stable through year 3**
- **Patient-reported functional impairment related to skin symptoms also improved, with a similar pattern**

Effects on Other Symptoms







- **Skin damage increased while CDASI activity score improved from moderate-severely active to more mildly active disease. Then, as skin disease activity remained low, skin damage improved slowly over then next 2 years in the OLE.**
- **Itch and pain interference symptoms also improved during the first 12-15 months of the OLE, then a durable response was observed through then end of 3 years**

Adverse Events

- Mean (SD) exposure of subjects to lenabasum was 1048 (273.6) days, range or slightly less than 3 years

Number of subjects with	Number (%)
Any AE	20 (100)
Death	0
Any SAE	0
Any AE leading to study discontinuation (unrelated metastatic prostate cancer)	1 (5)
Any AE by maximum severity	
Mild	16 (80%)
Moderate (1 actinic keratosis, 1 sinusitis and DM flare)	2 (10%)
Severe (fatigue, metastatic prostate cancer)	2 (10%)
Any AE by strongest relationship	
Unrelated	13 (65%)
Possibly related (5 mild, 1 mod sinusitis)	6 (30%)
Probably related (1 mild fatigue)	1 (5%)

- **The most common AEs (severity) were: fatigue (4 mild, 1 severe); dizziness (3 mild); DM flare (2 mild, 1 moderate); URI (3 mild) sinusitis (1 mild, 1 moderate) and 2 each (all mild) of common cold, herpes zoster, nausea, numbness, and UTI**

Conclusions

- **Lenabasum was safe and well-tolerated in study JBT101-DM-001 through Week 155 of the OLE. There were no severe AEs and no study discontinuations related to lenabasum**
- **Improvement in multiple efficacy outcomes was observed through year 1 in the OLE, with stability or continued improvement thereafter**
- **Limitations of ascribing efficacy to lenabasum during the OLE are acknowledged, especially in the setting of background immunosuppressive treatments**
- **A Phase 3 study testing safety and efficacy of lenabasum in DM is complete and results are pending**

Thank You

- **The people with DM who participated in this study**
- **Study staff**

Disclosures

- Dr. Werth reports grants from Corbus Pharmaceuticals and from NIH
- This study was sponsored by Corbus Pharmaceuticals, Inc.