Clinical Outcomes Among Participants with Diffuse Systemic Sclerosis Contracting COVID-19 During Clinical Studies of Lenabasum: A Case Series

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Systemic Sclerosis & Related Disorders Clinical Poster #3

Background

- Lenabasum is an oral, non-immunosuppressive, cannabinoid receptor type 2 (CB2) agonist that resolves inflammation and limits fibrosis in animal and human models of disease.
- Patients with systemic sclerosis (SSc) may be at increased risk for bad outcomes with COVID-19, given the high rate of immunosuppressive medication use, underlying lung pathologies, and accompanying co-morbid conditions.
- Limited data are available on outcomes of COVID-19 infection in these patients.1,2
- The American College of Rheumatology (ACR) and the European League Against Rheumatism (EULAR) are collecting provider-entered COVID-19 cases in a registry of patients with rheumatic diseases.3,4

Objective

- We report **the** number and outcomes of COVID-19 cases in regularly monitored diffuse cutaneous (dc) SSc patients followed in 2 open-label extension (OLE) studies of lenabasum, an orally-administered, non-immunosuppressive, selective cannabinoid receptor type 2 (CB2) agonist.

Methods

- This cohort included participants satisfying ACR/EULAR criteria for SSc who were receiving lenabasum 20 mg BID in the OLE studies in a Phase 2 (NCT02465437) or Phase 3 trial (NCT03398837).
- Background therapy with immunosuppressive medications was allowed. COVID-19 infection rate was discerned by review of adverse events (AEs) and required a positive COVID-19 **PCR** test.
- Outcome of COVID-19 was provided by treating physicians.

Results

Table 1. Summary of clinical characteristics of dcSSc study participants with COVID-19

Age Gender Race Serology	ILD (Yes/No) by CXR or HRCT; (Last $ppFEV_1$)	Concomitant Illness	Background Immuno-suppressive	Positive COVID-19 Test (Yes/No)	Status of Study Treatment	Patient Course	Anti-viral Treatment (Yes/No)	Serious AE (Yes/No)	Current Patient Status
40 male white ARA	No	Psoriasis	MMF*	Yes	Lenabasum 20mg BID* continued	Symptomatic with low grade fever, aches, nasal discharge, cough, and sweating. ER visit for chest tightness with a decreased aO_2 sat at 87% which increased to 94% on 1 L O_2; discharged home with O2 for 4 days	No	No	Recovered
77 female white ARA	Yes by HRCT (81%)	Asthma	MMF, methyl-prednisolone	Yes	Lenabasum 20mg BID temporarily stopped for 22 days and then restarted after recovery	Symptomatic with fatigue, fever, chronic cough, myalgias, headache, vomiting; 3 days in hospital for hyponatremia, no ventilation.	Yes, blinded trial with remdesivir	Yes	Recovered
45 female white ARA	No	No	abatacept	Yes	Lenabasum 20 mg BID continued; abatacept held	Symptomatic with fatigue, myalgia, and cough; evaluated in ER without receiving oxygen and discharged to home with self-quarantine	No	No	Recovered
47 male white ATA	Yes by HRCT (77%)	No	MMF	Yes	Lenabasum 20mg BID continued; MMF held	Asymptomatic tested for positive contact; treated with home self-quarantine	Hydroxy-chloroquine	No	Asymptomatic

Abbreviations: dcSSc (diffuse cutaneous systemic sclerosis), ATA (anti-topoisomerase-1 antibody), ARA (anti-RNA polymerase III), ILD (interstitial lung disease), CXR (chest X-ray), HRCT (high resolution computed tomography), M (male), F (female), W (white), MMF (mycophenolate mofetil), BID (twice daily)

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Conclusions

- The rate of confirmed COVID-19 infections (0.11%) in this cohort of dcSSc patients is about the same as the rate estimated from CDC data of June 5, 2020, adjusted for age (~0.1%).
- This suggests the diffuse cutaneous SSc subjects in this cohort are not more vulnerable to COVID-19 infection than the general population.
- All 4 trial participants despite 2 with confirmed ILD had acceptable outcomes, in the context of continued or resumed lenabasum treatments.

References

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Thank You

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- Members of the Steering Committee
- Members of the Data Monitoring Committee

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