Safety and Efficacy of Lenabasum in Refractory Skin-Predominant Dermatomyositis Subjects
Treated in an Open-Label Extension of Trial JBT101-DM-001

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ABSTRACT
Lenabasum (JBT101) is an oral selective CB2 receptor agonist under development for the treatment of dermatomyositis and systemic sclerosis. Lenabasum label dosing is acknowledged. These data support further testing of lenabasum in dermatomyositis.

BACKGROUND
Lenabasum (JBT101) is a small-molecule CB2 receptor agonist that acts as a dual modulator of innate and adaptive immunity. Open-label extension of JBT101-DM-001

STUDY DESIGN AND SUBJECT CHARACTERISTICS
N = 24 Predominant Dermatomyositis Subjects

ADVERSE EVENTS DURING OPEN-LABEL DOSING

CDASI activity score improved (decreased) during the OLE, with mean (SE) change from baseline in CDASI activity score of –13.7 (-6.3) at 12 months. Improvement was seen in 58.3% of subjects. 96% of subjects achieved an improvement in CDASI activity score of ≥10 points or more.

Patient Global Assessment of Disease Activity, 10-cm VAS

Promising 29 Symptoms

EFFECTS ON SKIN DISEASE

CDASI activity score improved (decreased) during the OLE, with mean (SE) change from baseline in CDASI activity score of –13.7 (-6.3) at 12 months. Improvement was seen in 58.3% of subjects. 96% of subjects achieved an improvement in CDASI activity score of ≥10 points or more.

Patient Global Assessment of Disease Activity, 10-cm VAS

Physician Global Assessment of Disease Activity, 10-cm VAS

EFFECTS ON OVERALL DISEASE

Overall disease activity improved during the OLE, as assessed by both the patient and the physician.

Improve was still continuing at Month 12

EFFECTS ON QUALITY OF LIFE AND FUNCTION

CDASI activity score improved (decreased) during the OLE, with mean (SE) change from baseline in CDASI activity score of –13.7 (-6.3) at 12 months. Improvement was seen in 58.3% of subjects. 96% of subjects achieved an improvement in CDASI activity score of ≥10 points or more.

Improvement was still continuing at Month 12

In the 12 subjects that experienced AEs related to lenabasum in the OLE, 10 of them had no changes in their skin disease.

SUMMARY AND CONCLUSIONS

All subjects who entered the OLE completed 12 months of dosing.

There have been no serious AEs related to lenabasum and no deaths in the study to date.

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Immunosuppressive Drugs

10 subjects had no changes during the OLE. Only 1 subject had AEs related to lenabasum and no deaths in the study to date.

Improvements (decreases) in patient-reported pain 10-cm VAS, physician-reported pain 10-cm VAS, and physician global assessment 10-cm VAS were seen during the OLE. Improvements in PROMIS physical function score were also seen during the OLE.

SUMMARY AND CONCLUSIONS

There have been no serious AEs related to lenabasum and no deaths in the study to date.

All subjects who entered the OLE completed 12 months of dosing.

Immunosuppressive Drugs

12 subjects had no changes during the OLE. Only 5 subjects had AEs related to lenabasum and 1 subject died. In the 12 subjects that experienced AEs related to lenabasum during the OLE, 10 of them had no changes in their skin disease.

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To obtain this study in full, please contact the authors directly.