Sinclair DERMATOLOGY

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RECRUITING NOW

A RANDOMISED, DOUBLE-BLIND, VECHILE-CONTROLLED EFFICACY AND SAFETY STUDY OF OLUMACOSTAT GLASARETIL GEL IN SUBJECTS WITH ACNE VULGARIS

Dermira, Inc. is investigating the efficacy and safety of Olumacostat Glasaretil Gel, 5.0%., a pro-drug of TOFA, sarcosine ester, as a topically applied sebum inhibitor for the treatment of acne vulgaris.

Inclusion Criteria:

a) Clinical diagnosis of facial acne vulgaris with at least 20 inflammatory lesions, **and** at least 20 non-inflammatory lesion**s**, **and** an Investigator Global Assessment of >3

b) Willing to refrain from using any other acne treatments for duration of study

c) Sexually active female patients of child-bearing potential MUST be willing to use oral contraception and this may NOT include OCP'S containing androgen receptor blockers (ie. Diane 35 and Jasmine).

d) Have NOT used oral retinoids within 12 months prior to first dose, or systemic corticosteroids, antibiotics or other systemic anti-acne drugs >4 weeks prior to first dose

Patients will be randomized to active treatment or placebo in a 2: 1 ratio. There are 5 visits over 12 weeks.

Upon completion of the trial patients may be eligible to rollover to a competitive 36-week extension study.

All treatments are provided free of charge. Other inclusion and exclusion criteria apply. Patients will receive $50 travel reimbursement per visit.

If you have any patients who are suitable, please ask them to call or email Samantha Dinning to schedule a screening visit. Her number is 0455 915 411. Her email address is: clinicaltrials@sinclairdermatology.com.au