Study of efficacy, safety and tolerability of crisaborole and PF-07038124 with and without NBUVB in vitiligo: A phase 2A randomized, double-blind, vehicle-controlled clinical trial

PI: Stanca Birlea, MD, PhD

Purpose: To determine the safety, effectiveness and tolerability of two PDE4i ointments (or vehicle), alone and in combination with active NBUVB (or sham NBUVB) in treating lesions of participants with non-segmental vitiligo

Eligible participants:

- Have vitiligo on the face and at least one other body area (total BSA 3-90%, facial BSA ≥0.25%)
- Are 18 to 75 years old
- Are not pregnant and are willing to avoid pregnancy throughout the study

What is involved?

- Study duration is 32 weeks
- 8 study visits (about 1 per month)
- Apply ointment to vitiligo-affected skin twice daily for 24 weeks
- Phototherapy sessions 3 times per week at home (Daavlin machine provided by CU) for 24 weeks

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Study Title: Study of efficacy, safety and tolerability of crisaborole and PF-07038124 with and without NBUVB in vitiligo: A phase 2A randomized, double-blind, vehicle-controlled clinical trial

Principle Investigator: Stanca Birlea, University of Colorado School of Medicine

Study Sponsor: Department of Dermatology, University of Colorado

Study Funder: Pfizer, Inc.

Purpose of the Research Study: To assess the efficacy, safety and tolerability of two PDE4i drug ointments (or of vehicle ointment) in combination with active Narrow Band UVB (NBUVB) (or sham NBUVB) in treating lesions of participants with non-segmental vitiligo

Main Procedures Involved: The research procedures include phototherapy with NBUVB, application of experimental medication, skin examinations by a dermatologist to measure changes in the skin's pigment, blood draws, and skin biopsies.

Main Inclusion/Exclusion Criteria:

Inclusion criteria

-Age 18-75 years
-A clinical diagnosis of non-segmental vitiligo for at least 3 months; *and*
-Body Surface Area affected (BSA) involvement of 3% - 90%, excluding vitiligo of scalp, palms/soles
-BSA ≥0.5% involvement of the facial area
-Participants must agree to treatment area involving 3-25% BSA

Exclusion criteria

-Certain medical conditions
-History of transplantation procedure for vitiligo
-History of skin bleaching treatment
-Certain concomitant therapies
-Pregnant women

Duration of Participation: 8 months

Compensation: Compensation provided for travel and skin biopsies

Contact information:

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