NIELSEN BioSciences Inc. Clinical Research Program

CFW-2D: Safety and Efficacy of Varying Regimens of CANDIN for Treatment of Common Warts (Verruca Vulgaris) NCT02393417

This is a placebo-controlled, double-blind, phase 2a study evaluating three different dosing regimens. Subject will be randomized to treatment with either CANDIN or placebo (3:1). Main study will be up to 20 weeks (10 doses administered every other week) or until a subject has complete resolution of all injectable common warts. Subjects who cannot tolerate dosing every 2 weeks due to a local tolerance issue may be injected at 3-week intervals for up to 10 doses, increasing the length of the study to 29 weeks. Subjects will be followed for 4 months after final injection(s) for evidence of new or reoccurring warts and for safety evaluation.

This study is investigational. The study has completed recruitment.

CANDIN is an approved skin test injection for detection of immunity to Candida albicans. It not approved for the treatment of warts or any other therapeutic use.

Inclusion Criteria:

1. Men or women between the ages of 18 and 65 years inclusively at time of consent
2. Subjects presenting with 3 to 20 injectable common warts (verruca vulgaris) for at least 12 weeks at the time of the Baseline Visit
3. Subject's common warts for injection must measure between 3 and 20 mm at Baseline Visit and be located on hands, feet (excluding soles), limbs, and/or trunk. Flat, plantar, facial, periungual, genital warts or warts in region of pre-existing inflammatory condition are excluded from injection
4. Subjects enrolled into Cohort 3 must have common warts for injection in at least 2 different anatomical regions defined as: left arm, right arm, left hand, right hand, left leg, right leg, left foot (excluding sole), right foot (excluding sole) and torso
5. Subject, male or female is willing to use effective contraceptive method for at least 30 days before the Baseline Visit and at least 30 days after the last study drug administration unless not of childbearing potential
6. Mentally and legally capable of giving informed consent prior to any study related procedures

Exclusion Criteria:

1. Presence of systemic or localized diseases, conditions, or medications that could interfere with assessment of safety and efficacy or that compromise immune function including psoriasis
2. Subject has been diagnosed with diabetes mellitus or a history of keloid formation
3. Injectable common wart(s) located in areas with existing dermatologic conditions or with an underlying inflammatory conditions, or tattoos or implants/piercing/hardware or marking that may conceal responses or reactions are excluded from injection
4. Existing/planned pregnancy, childbirth in the past six months prior to the Baseline Visit, or breast feeding, or plan on donating eggs or sperm during the study and in the month following the last injection
5. Treatment of warts within 4 weeks of the Baseline Visit OR treatment of warts with therapies that produce an immune response within 12 weeks of the Baseline Visit
6. Recalcitrant warts defined as those not successfully treated by five or more treatments (excluding OTC treatments).
7. Abnormal (low < 5 mm or high >25 mm) baseline result to the Delayed Type Hypersensitivity (DTH) test
8. Subject has a condition or treatment resulting in being immunocompromised
9. Treatment with cimetidine, certain zinc supplements, or an immunosuppressive drug within 12 weeks of the Baseline Visit
10. Subject has used any investigational agent within 30 days prior to the Baseline Visit or within 5 half-lives of that investigational agent prior to the Baseline Visit (whichever is longer)
11. Previous treatment of warts with any type of intralesional injection with candida extract (including CANDIN)