CLINICAL TRIAL REVIEW

Clinical Trial Review is a JDD department designed to provide physicians with information on drugs and devices undergoing clinical testing. It is our goal to inform the reader of the status of select drug and device studies relevant to the practice of dermatology before this information is available through standard channels. To participate in or learn more about these and additional trials, visit www.clinicaltrials.gov.

Phase IIa, Randomized, Double-Blind, Placebo-controlled, Multicenter Study to Assess the Safety, Tolerability, and Preliminary Efficacy of MEDI8968 in Subjects With Moderate to Severe Hidradenitis Suppurativa

Sponsored by AstraZeneca, the purpose of this study is to gain initial evidence for the safety, tolerability and efficacy of MEDI8968 for the treatment of subjects with moderate to severe hidradenitis suppurativa. The primary outcome measures include a proportion of subjects achieving a clinically relevant response in Physician Global Assessment (PGA), with score 0, 1, or 2 from baseline to 12 weeks, and a proportion of subjects achieving a clinically significant response measured by the proportion of subjects who achieve 0, 1, or 2 PGA by the end of week 12. Other outcomes include subject's global Impression of change reported on PGIC scale (1-7 point scale ranging from 1 "very much improved" to 7 "very much worse") over 12 weeks, and the proportion of subjects achieving a clinically significant response measured by the proportion of subjects who are "minimally improved", "much improved", or "very much improved" on the Patient's Global Impression of Change (PGIC).

Patients must have a diagnosis of HS for at least 1 year and at least 5 active inflammatory lesions in at least 2 locations.

Condition	Experiment
Hidradenitis Suppurativa	Safety/Efficacy Study
Study ID Numbers: D5440C00001 **ClinicalTrials.gov Identifier:** NCT01838499	

High Risk Cutaneous Squamous Cell Carcinoma Treated With Mohs Surgery Randomized to Elective Management of the Draining Lymph Nodes vs Periodic Clinical Nodal Observation

Sponsored by City of Hope Medical Center, this trial will comprehensively evaluate the human papillomavirus (HPV) vaccine in cancer survivors between 9 and 26 years of age by (1) determining the prevalence of HPV vaccine initiation among young cancer survivors, and (2) determining the immune response to and safety/tolerability of the quadrivalent HPV vaccine in young cancer survivors.

The primary objectives are will use a cross-sectional survey approach, estimate the prevalence of HPV vaccine non-initiation: Examine sociodemographic, behavioral, and medical determinants of HPV vaccine non-initiation. Using a single-arm, phase II, open-label, prospective longitudinal trial design, to evaluate the 3-dose quadrivalent (qHPV) vaccine series and measure the following endpoints: a) Determine immunogenicity following the third and final vaccine dose; b) Identify clinical/host factors influencing immunogenicity; c) Determine the safety/tolerability of the qHPV vaccine in cancer survivors. Evaluate the persistence of antibody response at 2 years post vaccine initiation and identify clinical/host factors influencing response persistence.

Patients for the survey must be a cancer survivor, and between 12 and 60 months after completion of cancer therapy (chemotherapy, radiation, hematopoietic cell transplant [HCT]).

Condition	Experiment
Human Papilloma Virus Infection	Prevention (vaccine therapy)
Study ID Numbers: 11034, NCI-2011-03654, 1R01CA166559, Merck-IISP#40083 **ClinicalTrials.gov Identifier:** NCT01492582	

Phase II, Randomized, Double Blinded, Placebo Controlled, Multiple-dose Regimen Study to Assess the Rate of Histological Clearance and Effect on Molecular Pathways as Well as on Biomarkers of 12 Months Secukinumab 300 mg s.c. Treated Patients With Chronic Plaque-type Psoriasis

Sponsored by Novartis, This study is designed to evaluate the proportion of patients achieving reversal of chronic plaque psoriasis at week 4 and 12 following multiple doses of secukinumab administered subcutaneously (sc) compared to placebo. Starting from week 13, all patients will receive multiple doses of secukinumab up to week 52 to study long term effects of secukinumab. Clinical endpoints including biomarker assessments, PASI, IGA, and DLQI will be compared to better understand, why secukinumab may be effective in psoriasis patients. The primary outcome measure is for patients to achieve skin histology response after secukinumab treatment after 12 weeks of treatment.

Patients being tested have chronic plaque-type psoriasis diagnosed for at least 6 months, moderate to severe psoriasis as defined by: PASI score of ≥12, IGA score of ≥3, BSA (body surface area) affected by plaque-type psoriasis of ≥10%, and chronic plaque-type psoriasis considered inadequately controlled by: topical treatment and/or; phototherapy and/or previous systemic therapy.

Condition	Intervention
Psoriasis, Plaque-type Psoriasis	**Drug:** secukinumab and placebo
Study ID Numbers: CAIN457A2223 **ClinicalTrials.gov Identifier:** NCT01537432	