CLINICAL TRIAL REPORT

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.

PLAQUE PSORIASIS

A Long Term Study to Evaluate the Safety and Tolerability of CP-690,550 for Patients With Moderate to Severe Chronic Plaque Psoriasis

Sponsored by Pfizer, the main objective of this study is to evaluate the long-term safety of CP-690,550 in patients being treated for moderate to severe chronic plaque psoriasis. This is an open label extension study available to patients who participated in one of the qualifying studies with CP-690,550, providing entry criteria are met.

The study is anticipated to continue for up to at least 2 years post First Market Approval (FMA) in a global, major market. All subjects will receive 10 mg BID of CP-690,550 for the first 3 months of the trial. The study has the option for variable dosing with 5 mg or 10 mg BID after first 3 months of treatment based on PI discretion.

Primary outcome measures include incidence and severity of adverse events, incidence of clinical laboratory abnormalities, change from baseline (in this and/or prior study) in clinical laboratory values, and changes in physical examination from baseline during treatment (Time frame: month 1, month 3, and every 3 months thereafter until approximately April 2017).

Condition	Intervention
Plaque psoriasis	**Drug:** CP-690,550
Study ID Numbers: A3921061, 2010-020002-15 **ClinicalTrials.gov Identifier:** NCT01163253	

FACIAL LIPOATROPHY

Voluma Filler Agent for the Treatment of HIV-Associated Facial Lipoatrophy

Sponsored by the VA Northern California Health Care System in collaboration with Allergan, the purpose of this study is to test the safety of Voluma and see what effects it has on HIV facial lipoatrophy. The hypothesis is that Voluma will be safe and efficacious, and positively impact the quality-of-life in the treatment of facial lipoatrophy in patients with HIV.

HIV facial lipoatrophy (volume loss) is an increasing concern with patients on Highly Active Anti-Retroviral Therapy (HAART) because it affects the quality-of-life and adherence to medication regimen. Treatment of HIV facial lipoatrophy helps to improve patient wellness by removing the social stigma associated with HIV facial lipoatrophy. Currently, there are few medical therapies that can treat HIV facial lipoatrophy and are FDA-approved for this indication.

Voluma is the only agent that is FDA-approved for facial volume loss. The investigators anticipate Voluma having fewer adverse effects than current FDA-approved drugs for HIV lipoatrophy as Voluma is a hyaluronic acid (HA)-based agent. The benefit of using hyaluronidase to "correct" or "modify" facial HA-based volume therapy is also a benefit for HIV patients, which currently does not exist as a post-injection modification option for other FDA-approved filling agents used to treat patients with HIV facial lipoatrophy.

Condition	Intervention
HIV Facial Lipoatrophy	**Intervention Device:** Voluma
Study ID Numbers: Allergan-97727 **ClinicalTrials.gov Identifier:** NCT02342223	

BURN INJURIES

A Comparison of Medihoney® Gel With Active Leptospermum Honey and Santyl® in the Treatment of Partial Thickness Burns

Sponsored by Allegheny Singer Research Institute, the objective of this study is to assess the efficacy of Medihoney® Gel with Active Leptospermum honey dressing relative to Santyl® ointment dressing on the time to heal, bacterial growth in the wound, patient satisfaction, and treatment costs in patients with partial thickness burns.

It is hypothesized that, compared with Santyl®, Medihoney® gel with active leptospermum honey will result in significantly faster wound healing, its sites will yield significantly fewer positive cultures for Pseudomonas aeruginosa and other bacteria, its patients will provide significantly higher patient care satisfaction ratings, and its treatment costs will be significantly lower.

The inclusion criteria for this study are male or female new patients presenting with a partial thickness burn injury in at least two non-contiguous locations of the body; and their burn injury must have occurred within 72 hours of sustaining a burn.

Primary outcome measures are a change in wound appearance (Time frame: daily for 7 to 21 days, depending on the time it takes for the burn injury to completely heal).

Condition	Intervention
Burn injuries	**Intervention Device:** Medihoney® gel with active leptospermum honey and Santyl®.
Study ID Numbers: 13-021 **ClinicalTrials.gov Identifier:** NCT02250183	

ROSACEA

Mirvaso in Use Study

Sponsored by Galderma Laboratories, L.P., the purpose of this study is to assess the signs and symptoms of rosacea, including erythema, without treatment and during treatment with Mirvaso® gel. It is also designed to further characterize lifestyle impact and patient satisfaction with Mirvaso® treatment and gain a better understanding of the real-world use of Mirvaso® on the pattern and management of facial erythema of rosacea.

Subjects must have a board certified dermatologist (BCD) clinical diagnosis of facial erythema of rosacea and be eligible for treatment with Mirvaso® (brirnonidine) topical gel 0.33% per package insert. They must also have a CEA score of ~3 and fewer than 3 facial inflammatory lesions of rosacea at screening visit 1.

Primary outcome measures are clinical erythema assessment (Time frame: 14 days). Secondary outcomes include a subject facial redness questionnaire, a subject treatment satisfaction questionnaire, a facial redness VAS, and inflammatory lesions.

Condition	Intervention
Rosacea	**Drug:** Brimonidine
Study ID Numbers: GLI.04.SPR.US 10305 **ClinicalTrials.gov Identifier:** NCT02249065	

SKIN CANCER

Post Excision/Mohs Scar Laser Resurfacing

Sponsored by the Mount Sinai School of Medicine, this quantitative and qualitative scar analysis study will evaluate the potential benefits of treating a surgical scar post excision with an ablative fractionated CO2 laser with the goal of decreasing the appearance and size of the scar.

The objective of this research is to determine, through a split scar study, that treating a post excision scar with a fractionated ablative CO2 laser improves both the texture and cosmetic appearance of the scar. An attempt will be made to determine the ideal timing for treating the excision scar as previous studies have ranged from treating the day of the excision up till 10 weeks post-excision. In order to evaluate the treated portion versus untreated portion of the scar, investigators and the subjects will use a quartile rating scale. In addition, punch biopsy samples will be taken to quantify the difference in collagen architecture 9 weeks after treatment with the laser.

There will be a total of 7 study visits to include the day of the excision and laser treatment if randomized to this group, post-op day 10 for suture removal as well as laser therapy if the subject has been randomized to that treatment group, 4 weeks post-op, 9 weeks post-op and laser treatment for subjects randomized to this time frame for treatment, 12 weeks post-op, 17 weeks post-op, and 24 weeks post-op. Healing and scar appearance will be reviewed and rated at each of the 6 postsurgical visits.

Condition	Intervention
Skin cancer	**Drug:** Laser Treatment
Study ID Numbers: GCO 14-0387 **ClinicalTrials.gov Identifier:** NCT02130297	

PEDIATRIC PSORIASIS

Study Evaluating the Safety and Effectiveness of Etanercept for the Treatment of Pediatric Psoriasis

Sponsored by Pfizer, this study is a long-term, prospective, observational cohort study of the safety and effectiveness of Etanercept in the treatment of pediatric psoriasis patients in a naturalistic setting. The aim of this study is to assess the safety and effectiveness of Etanercept for the treatment of pediatric psoriasis in Europe.

Etanercept is a biologic drug and has been licensed for the treatment of chronic severe plaque psoriasis in children and adolescents who are inadequately controlled by, or are intolerant to, other systemic therapies or phototherapies. There are limited data available about the long-term effects of etanercept in pediatric psoriasis, especially with respect to malignancy.

Patients aged 4-17 with plaque psoriasis diagnosed by a dermatologist will be invited to participate in the registry only after a clinical decision has been made to prescribe Etanercept. The safety of the drug and how well the drug works will be evaluated during the follow-up period. The follow-up period will last 5 years and patients will be followed up every 3 months for the first 2 years and every 6 months for the next 3 years.

Condition	Intervention
Pediatric psoriasis	**Drug:** Etanercept
Study ID Numbers: 0881X1-4654, B1801035 **ClinicalTrials.gov Identifier:** NCT01100034	