Vaseline Initiative Aims to Close Skin Heath Treatment Gap

The Vaseline Healing Project in partnership with non-profit Direct Relief is working to close the skin health treatment gap for Americans by providing skin care and training along with Vaseline products and medical supplies for those with limited access.

The Vaseline Healing Project traveled with actress and project advocate Viola Davis to her hometown of Central Falls, RI to host a one-day community health fair on October 8.

Five local dermatologists and health clinicians, including Vaseline Healing Project advisory board member and board certified dermatologist Grace Bandow, MD, of Bristol, RI, treated hundreds of residents during the one-day health clinic presented by The Vaseline Healing Project. Residents were provided access to skin screenings and skin checks in addition to medical counsel and other medical services such as dental care, flu shots, and screenings for blood pressure and glucose levels. The free community event also featured food, live entertainment and special exhibits from local businesses.

Throughout 2016, every Vaseline lotion or jelly purchase (excluding lip tins) will support Direct Relief to deliver Vaseline Jelly, medical supplies, and dermatological care to people affected by poverty or emergencies up to a maximum of $1 million dollars.

Indoor Tanners Exhibit Poor Outdoor Sun Protection Practices, Too

Adults who frequently tan indoors aren’t great about protecting their skin outdoors or undergoing skin cancer screening either, according to a new study published online by JAMA Dermatology.

Alexander H. Fischer, MPH, of the Johns Hopkins University School of Medicine in Baltimore, and coauthors used 2015 National Health Interview Survey data for a study population of 10,262 non-Hispanic white adults ages 18 to 60 without a history of skin cancer. The analysis was limited to non-Hispanic white adults because of their high prevalence of indoor tanning and high incidence of skin cancer.

Among 10,262 adults (49 percent female), 787 (7 percent) reported having tanned indoors within the past year; 3.6 percent reported moderate indoor tanning (one to nine times in the past year) and 3.4 percent reported frequent indoor tanning (10 times or more in the past year).

In the overall study population, more frequent tanning bed use was associated with poor use of sunscreen, protective clothing, and shade and it was associated with having had multiple sunburns in the past year. Among young people 18 to 34, those who frequently tanned indoors were more likely to report rarely/never wearing protective clothing and rarely/never seeking shade on a warm sunny day compared with those who did not tan indoors, the study showed.

Women who frequently tanned indoors were more likely to report rarely/never applying sunscreen, rarely/never wearing protective clothing, rarely/never seeking shade, and multiple sunburns in the past year compared with women who did not tan indoors. Men who frequently tanned indoors were more likely to rarely/never seek shade seek shade and men who moderately tanned indoors were more likely to rarely/never use protective clothing and to report multiple sunburns in the past year compared with
men who did not tan indoors.

Moreover, people who tanned indoors were not more likely to have undergone a full-body skin examination compared with those adults who do not tan indoors. “These results demonstrate that many individuals who tan indoors may not acknowledge the long-term risks associated with increased UV exposure. Thus, these findings highlight the importance of not only emphasizing avoidance of indoor tanning in public health messages and physician communication, but also reiterating the need for sun protection and skin cancer screening in this population,” the study concludes.

Allergan Completes Vitae Tender Offer

Allergan completed their tender offer to purchase all outstanding shares of Vitae Pharmaceuticals, Inc., a clinical-stage biotechnology company. A tender offer occurs when an acquiring company offers to buy another company’s stock from shareholders at a specified price. The next step is a merger. Allergan offered to purchase all outstanding shares of Vitae for $21.00 per share, in cash, for a total transaction value of approximately $639 million.

The acquisition strengthens Allergan’s dermatology product pipeline, with the addition of VTP-43742, a phase 2 first-in-class, orally active RORγt (retinoic acid receptor-related orphan receptor gamma) inhibitor for the potential treatment of psoriasis and other autoimmune disorders. The acquisition also adds VTP-38543, a phase 2a topical LXRβ (Liver X Receptor beta) selective agonist for the potential treatment of atopic dermatitis. VTP-38543 may work by decreasing inflammation in damaged skin tissue and repairing the damaged outer layer of skin. The deal also adds Vitae’s Contour structure-based drug design platform aimed at discovering product candidates for validated therapeutic targets where biopharmaceutical research and development has traditionally struggled to develop drugs due to challenges related to potency, selectivity, and pharmacokinetics.

Biosim Update: Pfizer to Begin Shipping INFLECTRA in Late November 2016

Pfizer Inc. will begin shipment of INFLECTRA (infliximab-dyyb) for injection, a biosimilar of REMICADE (infliximab) to wholesalers in the United States in late November 2016. INFLECTRA will be the first biosimilar monoclonal antibody (mAb) and only the second biosimilar to be available in the US. It is approved for the treatment of:

- adult patients and pediatric patients (ages six years and older) with moderate to severely active Crohn’s disease who have had an inadequate response to conventional therapy;
- adult patients with moderate to severely active ulcerative colitis who have had an inadequate response to conventional therapy; and
- moderate to severely active rheumatoid arthritis in combination with methotrexate; active ankylosing spondylitis; active psoriatic arthritis; and chronic severe plaque psoriasis.

Pfizer holds exclusive commercialization rights to Celltrion’s INFLECTRA in the US, and has already introduced INFLECTRA in other markets across the globe. INFLECTRA will be introduced at a 15 percent discount to the current wholesaler acquisition cost (WAC) of REMICADE, its reference product. WAC is not inclusive of discounts to payers, providers, distributors and other purchasing organizations.

Study Calls Attention to Negative Impact, Need for Treatment of SK

Patients with asymptomatic seborrheic keratosis (SK) are bothered by highly visible skin lesions and are very interested in treatment to improve their appearance, even if a cost were associated with treatment, according to a new study conducted in dermatology practices by Burke, Inc. on behalf of Aclaris. Results from the study were presented at the annual Fall Clinical Dermatology Conference in Las Vegas.

The study included 406 patients aged 40-69 with asymptomatic SK lesions in 10 regionally-diverse community dermatology practices who completed questionnaires in their dermatologists’ offices.

The majority of patients (61 percent) took action to hide, disguise, or deal with their SK lesions (e.g., hiding them with clothes, makeup or hair, or picking at lesions so they fall off), the study showed. Approximately one-third (34 percent) of patients had previously asked their dermatologist about treatment for SK, motivated by concerns about appearance as well as health. Moreover, a vast majority of patients (86 percent) indicated they were somewhat or extremely interested in treatment provided in a dermatologist’s office and were willing to pay a reasonable out-of-pocket fee.

Factors that correlated with higher interest in treatment
PEOPLE ON THE MOVE IN DERMATOLOGY

CT DERMATOLOGIST TO CHAMPION AVON’S ANEW BRAND

Kim Nichols, MD, is Avon’s new consulting dermatologist. In her role, the Greenwich, CT-based dermatologist will help to educate Avon Representatives on the technology behind the ANEW brand, Avon’s flagship skincare line. The brand’s partnership with Dr. Nichols coincides with the launch of ANEW Ultimate Supreme Advanced Performance Crème, which is formulated with Celluvive complex and Tahitian black pearl essence. This lightweight night cream helps to minimize lines and repair damage on the skin’s surface.

BRENTON L. SAUNDERS IS ALLERGAN’S NEW CHAIRMAN OF THE BOARD

Brenton L. Saunders is Allergan’s new Chairman of the Board, the company reports. Effective immediately, Mr. Saunders will replace Paul Bisaro, who served as Executive Chairman since July 1, 2014. Mr. Bisaro will remain a member of the Allergan Board of Directors. In addition to the role of Chairman, Mr. Saunders will retain his current role as Chief Executive Officer and President. Also, effective today, Christopher Coughlin has been elected Lead Independent Director.

PAT ALTVILLA JOINS SUNEVA MEDICAL AS VP OF MARKETING

Suneva Medical, Inc., appointed Pat Altavilla as vice president of marketing. With more than 30 years of experience in the aesthetics and medical fields, Ms. Altavilla will oversee all marketing aspects for the company, further fortifying the brand’s strong leadership position.

Most recently, Ms. Altavilla worked for medical technology company Zeltiq Aesthetics Inc. where she served in numerous leadership roles including vice president of global physician and practice marketing and vice president, global strategic partnerships and practice development. With Zeltiq, she was instrumental in developing the brand’s global marketing organization as well as growing physician loyalty, enhancing practice development, launching innovative products, and increasing the company’s presence.

DR. KEN WASHENIK NAMED NEW PRESIDENT OF INTERNATIONAL SOCIETY OF HAIR RESTORATION SURGERY

The International Society of Hair Restoration Surgery (ISHRS), a global non-profit medical association and a leading authority on hair loss treatment and restoration, elected Ken Washenik, MD, PhD, FISHRS, as President. Dr. Washenik is Chief Medical Officer of Bosley Medical Group, a practice focused on medical hair restoration and hair loss solutions. Dr. Washenik has been on the ISHRS board for 5 years and in his new role, he will be leading 1,200 members across 70 countries worldwide. The ISHRS offers continuing medical education to physicians who specialize in hair transplant surgery and promotes and funds research in the area of hair restoration.

Dr. Washenik has published scientific and medical articles in peer review journals including Endocrinology, Journal of the American Academy of Dermatology, Archives of Dermatology, The Lancet and The New England Journal of Medicine to help further education and collaboration within the field.

Prior to his role at Bosley Medical Group, he was director of the Dermatopharmacology Unit at New York University School of Medicine. He continues to serve as a faculty member in the Department of Dermatology. Dr. Washenik received his PhD in cell biology from Baylor College of Medicine with a focus on hormone metabolism.

Cynosure Promotes Doug Delaney to Chief Commercial Officer

Cynosure, Inc. promoted Douglas J. Delaney, Executive Vice President of Worldwide Sales, to Chief Commercial Officer (CCO). In his new role, Mr. Delaney will lead all sales and revenue initiatives across the company, including identifying new revenue sources and driving new opportunities for growth. He reports to Michael Davin, President and Chief Executive Officer.

A seasoned executive with more than 25 years of experience in the aesthetic laser and medical equipment markets, Mr. Delaney joined Cynosure in 2003 as Director of North American Sales. He became Vice President of North American Sales in 2004 and was promoted to Executive Vice President of Sales in 2005. In June 2013, Mr. Delaney was promoted to Executive Vice President of Worldwide Sales. Before joining Cynosure, he was national sales manager at Cutera, Inc.

Valeant Appoints Chief Quality Officer

Valeant Pharmaceuticals International, Inc. appointed Louis W. Yu, PhD to the newly created position of Chief Quality Officer, Global Quality. Dr. Yu reports to Joseph C. Papa, Chairman and CEO of Valeant. As a new member of Valeant’s Executive Committee, Dr. Yu will oversee all aspects of quality and regulatory compliance for all of Valeant’s global businesses and operating sites. Dr. Yu joins Valeant with more than 30 years of leadership experience in the Quality and R&D functions of generic and branded pharmaceutical companies.
were the presence of lesions on the face or neck, the study showed.

While no SK treatment has been approved by the FDA, invasive procedural treatment options include cryosurgery, electrodessication, curettage, and surgery. Aclaris Therapeutics, Inc. is developing A-101, a proprietary high-concentration hydrogen peroxide topical solution with the potential to become the first FDA-approved treatment for SK. A-101 is about to complete pivotal phase 3 studies.

**FDA Clears Merz Aesthetics’ Cellfina System for Long-Term Improvement of Cellulite**

The FDA has cleared the Cellfina System from Merz Aesthetics, a division of Merz North America, for the long-term improvement in the appearance of cellulite on the buttocks and thighs of adult females with no loss of benefit for up to 3 years.

Cellfina is the only FDA-cleared minimally invasive procedure clinically proven to improve the appearance of cellulite for results that last at least three years, the longest duration of any device cleared by the FDA. The Cellfina System combines advanced, proprietary technology with subcision, to treat the structural cause of cellulite. According to market research, 78 percent of US women have cellulite that would qualify as treatable with the Cellfina System.

“I’ve been involved with the Cellfina System since it was first conceived as a potential treatment for cellulite. It’s been incredibly gratifying to see the treatment perform beyond the research setting,” said Dr. Michael Kaminer, Associate Clinical Professor of Dermatology, Yale Medical School. “The Cellfina System has truly been the only cellulite treatment that has delivered on its initial potential, providing women with a safe and effective treatment for their cellulite.”

The recent clearance by the FDA was a result of a prospective, multicenter US clinical study of 55 patients that underwent a single treatment with the Cellfina System. The Cellfina System improved the appearance of cellulite in 98 percent of treated patients at three years, according to independent physician evaluators. Importantly, 93 percent of patients reported satisfaction with their treatment at the three-year mark, and noticeable improvement on the Global Aesthetic Improvement Scale (GAIS) was seen in 100 percent of treated patients at three years.

No serious device-related adverse events were reported at any time during the pivotal trial and follow up.

**Novan Presents Phase 2b Data for SB204 Gel**

Results from Novan’s Phase 2b clinical trial to evaluate the efficacy and safety of topical nitric oxide-releasing product candidate SB204 gel for the treatment of acne vulgaris were presented at 35th Anniversary Fall Clinical Dermatology Conference in Las Vegas.

“In more than 30 years of experience as a dermatologist, I have seen firsthand how the tolerability of a topical acne product drives patient compliance,” said M. Joyce Rico, MD, Chief Medical Officer of Novan. “The safety and tolerability profile observed in the Phase 2b clinical trial with SB204 was excellent. Of all five tolerability assessments, the burning/stinging and scaling categories reflected the most notable difference between active and vehicle. Patients treated with SB204 rarely developed moderate (<3%) or severe (1%) burning/stinging at any point during treatment, while the incidence of moderate scaling never exceeded 1%.”

Novan’s two, identically designed phase 3 pivotal clinical trials for SB204 were fully enrolled as of September. Novan expects to report top-line results from these phase 3 trials in the first quarter of 2017.

**Volbella XC for Lips Now Available**

Allergan’s Juvéderm Volbella XC is here. The newly approved filler is now available for lip augmentation and correction of perioral rhytids in adults over the age of 21. Physicians can purchase Volbella XC after completion of an online training program at volbellatraining.com.

In clinical trials, Juvéderm Volbella XC was found to effectively increase lip fullness and soften the appearance of lines around the mouth in a majority of subjects through one year.

Juvéderm Volbella XC is formulated with Vycross, a proprietary filler technology from Allergan, which yields smooth products that have been engineered to address specific patient concerns.
The most common side effects observed in clinical trials were temporary responses at the treatment site such as swelling, tenderness, bruising, firmness, lumps/bumps, redness, pain, discoloration, itching and dryness. Most of these side effects resolved within 30 days.

**Oral Nalbuphine ER Performs Well in Phase 2 Trial of Prurigo Nodularis**

Trevi Therapeutics, Inc.’s Oral Nalbuphine ER reduced itch intensity and improved quality of life in prurigo nodularis patients, according to a phase 2 trial. Nalbuphine ER is an oral extended release mu receptor antagonist and kappa receptor agonist. Both modalities have been shown to be effective in treating itch. The Company is pursuing two conditions for clinical development: uremic pruritus and prurigo nodularis. Trevi is preparing for an end of phase 2 meeting for prurigo nodularis, has already held an end of phase 2 meeting with FDA for uremic pruritus, and will initiate phase 3 trials in both conditions in 2017.

The phase 2 three-arm study evaluated the safety and anti-pruritic efficacy of Nalbuphine ER tablets dosed twice-daily at 90mg and 180mg in 62 patients in the United States and Europe. Patients with moderate-to-severe itch intensity, defined as ≥ 5 on the 0-10 Numerical Rating Score (NRS) scale, were enrolled to evaluate drug efficacy across a representative patient population for treatment of this chronic indication. The actual average baseline worst itch for enrolled patients was ≥ 8, indicating the severe nature of the disease.

The study consisted of a titration period of two weeks, followed by an eight-week blinded period on a fixed dose of drug or placebo, and a two-week wash-out period. At the end of the wash-out period, patients were eligible to roll over into a one-year open label extension study. The Company expects the open label extension study to be completed in the third quarter of 2017.

The main outcome variables for this study were responder analyses of the proportion of patients with at least a 30 or 50 percent reduction in their 7-day worst-itch intensity NRS from baseline to completion of treatment at week 10 or last observation visit. The proportion of patients in the Nalbuphine ER 180 mg BID arm meeting 50 percent responder criteria at week 10 or last observed visit (MITT population with n=18) approached statistical significance (p=0.083), and this arm met statistical significance for patients (n=12) completing treatment (p=0.028). The mean change in worst itch NRS was additionally evaluated, and the MITT population of the Nalbuphine ER 180 mg BID arm as compared to placebo approached statistical significance (p=0.083) as well. This arm also met statistical significance for patients (n=12) completing treatment (p=0.025).

The ItchyQoL secondary endpoint, 22 questions that measure how pruritus affects a patient’s quality of life, provided supportive evidence of a favorable treatment effect on reduction in itch intensity compared to placebo. Change from baseline in the ItchyQoL total score was significantly more favorable for the Nalbuphine ER 180 mg BID dose compared to placebo (p=0.022), the study showed.

The most common adverse events in the study were dizziness, nausea, headaches, and fatigue, the majority of which were grade 1 or 2. As seen previously, the incidence rate of these events was similar to placebo after the titration period. No serious adverse events attributed to the drug were observed, and the study Data and Safety Monitoring Board raised no issues that affected the continuation of the study or required modification of study procedures.