practical dermatology NEWS
Volume 15, No. 10 • October 2018

Acne Stigma Linked to Lower Overall Quality of Life

Acne patients perceived social stigma negatively affects their quality of life, according to a new study from the University of Limerick.

In a survey of 271 people with acne, those respondents with negative perceptions of how society viewed their appearance had higher psychological distress levels and additional physical symptoms, such as sleep disturbance, headaches and gastrointestinal problems.

Females in the study reported greater impairment of life quality and more symptoms than males. Acne severity was significantly correlated with health-related quality of life and psychological distress, the study, published in *PLOS One*, shows.

University of Limerick researchers conducted the study to investigate whether acne sufferers' perceptions of stigmatization significantly predicts psychological and physical health outcomes; specifically health-related quality of life, psychological distress, and somatic symptoms.

According to the article's lead author, Jamie Davern, a lack of representation of people with acne in popular culture can increase the perceived stigma around the skin condition.

"Like many physical attributes that are stigmatized, acne is not well represented in popular culture, advertising or social media. This can lead people with acne to feel that they are 'not normal' and therefore negatively viewed by others. Online campaigns like #freethepimple and the recent 'acne-positive' movement emerging on social media is an encouraging development for people of all ages that are affected by acne," he explains.

"Importantly, the findings provide further support for the comparatively limited amount of studies investigating physical health problems experienced by acne sufferers. This is important information for clinicians dealing with acne conditions. It's also useful for those who are close to acne sufferers. The wider negative impacts some acne sufferers experience are very challenging and require sensitivity and support," Mr. Davern, a graduate student, concludes.

FDA Approves Paratek's Nuzyra

The FDA has approved Paratek Pharmaceuticals, Inc's Nuzyra (omadacycline) for the treatment of adults with community-acquired bacterial pneumonia (CABP) and acute skin and skin structure infections (ABSSSI). Nuzyra, a modernized tetracycline, is a once-daily IV and oral antibiotic that exhibits activity across a spectrum of bacteria, including Gram-positive, Gram-negative, atypicals, and drug resistant strains. The company plans on making Nuzyra available in the first quarter 2019.

The Centers for Disease Control and Prevention (CDC) estimates that drug-resistant bacteria cause two million illnesses and approximately 23,000 deaths each year in the United States. The main bacteria causing CABP, *Streptococcus pneumoniae*, is responsible for 1.2 million infections and 7,000 deaths, whereas ABSSSI is responsible for more than 750,000 hospitalizations. The increase of antibiotic resistance continues to drive the need for new, effective therapies.

The approval of Nuzyra is supported by multiple clinical trials within the company's global development program. Nearly 2,000 adult patients received Nuzyra and it was found to be efficacious and generally safe and well tolerated. As part of the approval, Paratek has agreed to conduct post marketing studies in CABP and pediatrics.

Seysara is First Oral Antibiotic Approved for Dermatology in 40 Years

Seysara (sarecycline), a new, first-in-class tetracycline-derived oral antibiotic, is now approved for the treatment of inflammatory lesions of non-nodular moderate to severe acne vulgaris in patients nine years of age and older. Almirall, which recently

almirall
The feel of science

acquired Seysara from Allergan, plans to launch the drug in January 2019.

Seysara is an oral tablet that is taken once daily with or without food. It has proven significant reduction of inflammatory lesions as early as three weeks after start of treatment and is generally safe and well tolerated.

"As dermatologists we are always seeking ways to improve the management of our patients' disease. The results of the studies are encouraging, with statistically significant efficacy vs placebo as early as 3 weeks. I'm looking forward to having this as an option for my patients when it becomes available in 2019," says Leon Kircik, MD, who participated in clinical trials for Seysara.

Seysara is expected to reach peak sales of $150-200 Million.

Veloce BioPharma Announces Positive Phase 2b Study Results for VBP-926 for Chemotherapy-Associated Paronychia

Veloce BioPharma, LLC, a clinical-stage biopharmaceutical company dedicated to developing topical therapeutics for unmet needs in dermatologic and ophthalmic diseases, shared positive results of its Phase 2b study of dilute povidone-iodine in a novel DMSO solvent system for the topical treatment of chemotherapy-associated paronychia, or painful and inflamed nail units resulting as a side effect of chemotherapy.

The multicenter, randomized, double-blind, vehicle-controlled Phase 2b study was designed to evaluate the safety, tolerability, and efficacy of two strengths of VBP-926 (1% PVP-I, 2% PVP-I) vs. vehicle in 102 subjects with chemotherapy-associated paronychia. Results from the study showed that VBP-926 (2%) met the primary efficacy endpoint of grade-improvement on the Paronychia Severity Grading Scale. Consistent with previously reported case series results, VBP-926 was well-tolerated at both doses and provided both morphological resolution and symptomatic relief in affected nails. VBP-926 is a broad-spectrum, resistance-free biocidal topical solution that has the ability to eradicate all known microorganisms including bacteria, viruses, yeasts, molds, fungi, and protozoa.

"This trial clearly demonstrated the clinical benefit of VBP-926 2% solution" says Kara Capriotti, MD, President and Director of Dermatology programs at Veloce. "We are well positioned to move VBP-926 into Phase 3 development and continue advancing a product that targets an indication with no approved therapies. Addressing the pain and discomfort suffered by patients with chemotherapy-associated paronychia is an enormous unmet need and we are encouraged to be getting closer to a topical therapy that can solve this problem."

Phase 2b results showed that VBP-926 at the higher concentration met the primary efficacy endpoint. The 2% dose reached statistical significance for nail grade improvement from baseline to the end of therapy for change in the Paronychia Severity Grading Scale (p=.0003). No treatment-related serious adverse events were reported. Adverse events were mild in severity and reversible when treatment was discontinued.

Allergan's Launches New Campaign: Juvéderm It

A new Juvéderm advertising campaign from Allergan aims to make this family of fillers a household name. Comprising a modernized logo, a bright color scheme, music, and robust social media component, "Juvéderm It" represents the first new advertising campaign in three years.

"Healthcare providers already know that Juvéderm is the No. 1 selling collection of dermal fillers, but consumers tend to think about 'fillers' as a general category. This bold, high-impact, new campaign will empower women to own their look and ask for Juvéderm by name," says Carrie Strom, Senior Vice President, US Medical Aesthetics for Allergan, in a news release. "The campaign is on television and in print, but it really comes alive online and on social media. We are already seeing healthcare providers posting about the campaign and encouraging their patients to Juvéderm It!"

Dermira's Qbrexa Cloth Now Available

Dermira, Inc.'s Qbrexa (glycopyrronium) cloth is now available to treat primary axillary hyperhidrosis. The new therapy is available in retail and community pharmacies nationwide. In June 2018, the once-daily, prescription anticholinergic was FDA approved to treat patients 9 years of age and older living with this chronic, medical skin condition.

To provide seamless and affordable access to Qbrexa, Dermira recently launched DermiraConnect. The program is designed to offer financial assistance and other customized

support services to eligible patients and healthcare professionals seeking to access Qbrexa.

To date, Dermira has secured coverage for approximately 53 percent of the total US commercial lives, exceeding its goal of securing more than 30 percent coverage by October 1, 2018 and 50 percent coverage by January 1, 2019. In addition to Express Scripts, Inc. and OptumRx, several other payers have also agreed to provide access to Qbrexa through their national formularies beginning October 1.

Nestlé to Explore Strategic Options for Nestlé Skin Health

As part of its regular strategy review earlier this year, the Board of Directors assessed Nestlé's Nutrition, Health and Wellness strategy. The Board fully confirmed the company's strategic direction and resolved to sharpen its focus on food, beverage, and nutritional health products.

After further analysis and consideration, the Board reported that it has come to the conclusion that the future growth opportunities of Nestlé Skin Health lie increasingly outside the group's strategic scope and has therefore decided to explore strategic options for Nestlé Skin Health. This review is expected to be completed by mid-2019.

Nestlé Skin Health provides science-based solutions to meet the specific skin health needs of healthcare professionals, patients and consumers with a range of medical and consumer brands through three complementary business units, including Epiduo and Soolantra in prescription, Restylane and Azzalure in aesthetics, and Cetaphil and Proactiv in consumer care.

Mark Schneider, CEO, commented: "Nestlé Skin Health has made significant progress under its new leadership team over the past two years. The company has developed convincing growth strategies for each of its business units and regained a competitive cost structure. Now is the right time to explore the best ownership structure for Nestlé Skin Health and to consider ways of taking it to the next level."

BY THE NUMBERS
$195 Million

The amount Allergan spent to acquire Bonti, Inc., a privately held clinical-stage biotechnology company focused on the development and commercialization of novel, fast-acting neurotoxin programs for aesthetic and therapeutic applications.

For more on this acquisition, look for next month's Aesthetics Management column with coverage from Joel Schlessinger, MD.

LEO Science & Tech Hub and Epicore Biosystems to Explore Wearable Skin Sensors to Improve Dermatologic Treatment Regimens

LEO Science & Tech Hub has established a new partnership with Epicore Biosystems focused on exploring the use of a non-invasive, wearable sweat sensor to measure prognostic biomarkers in real time, monitor patient response, and inform treatment decisions. The initial project will include a proof of concept study in collaboration with engineers and dermatologists at Northwestern University's Center for Bio-Integrated Electronics and Feinberg School of Medicine's Department of Dermatology to establish baseline measurements and milestones to validate the clinical relevance of the approach for patients with atopic dermatitis (eczema).

"A central goal of precision medicine is to predict early on if a given treatment will work for the individual patient. As atopic dermatitis (eczema) is a diverse skin disease, not all patients will benefit equally from a given treatment," says Michael Sierra, VP of the LEO Science & Tech Hub. "The possibility of enabling healthcare professionals to characterize skin hydration and disease-specific biomarker responses in real-time and in turn, helping them provide personalized treatment regimens for patients, is an extremely powerful concept. We believe that wearable technologies will have a major impact on the future of healthcare and LEO is fortunate for the opportunity to contribute our expertise in skin research and drug development to this project."

"The possibilities for driving targeted therapies based on high throughput and low-cost analysis of biomarkers in sweat are limitless," says Roozbeh Ghaffari, PhD, co-founder and CEO of Epicore Biosystems. "We're excited about our partnership with LEO Science and Tech Hub, and see it leading to new classes of wearable metabolic sensors that enable remote tracking of skin disease biomarkers and help accelerate interventions once patients leave the hospital."

"Sweat is a largely unexplored body fluid when it comes to disease biomarkers...Our vision, which is to develop an 'at-home-patch' test, will give patients the ability, early on, to determine if they benefit from a particular antibody treatment or need to try an alternative," says Troels Marstrand, Chief Data Scientist LEO Science and Tech Hub.

Since its launch, the LEO Science & Tech Hub has formed multiple collaborations to explore minimally invasive biomarker technologies, drug delivery devices, advanced imaging systems, and remote monitoring methods with research institutes and biotechnology companies including MIT, The Karp Lab, Novopyxis, Elektrofi and The Wellman Center for Photomedicine at Massachusetts General Hospital.

Ortho Dermatologics' Bryhali Lotion Receives Tentative FDA Approval for Plaque Psoriasis

The FDA has provided tentative approval of the New Drug Application for Bryhali (halobetasol propionate) Lotion, 0.01%, for the topical treatment of plaque psoriasis in adult patients. Bryhali Lotion is a new potent to superpotent corticosteroid that contains 0.01 percent halobetasol propionate in a novel vehicle lotion. Its safety has been established in clinical trials with dosing for up to eight weeks with no increase in epidermal atrophy. The final FDA approval for Bryhali Lotion is pending the expiration of exclusivity for a related product, which is expected in early November 2018. The company plans to launch Bryhali shortly thereafter, as scheduled, in November 2018.

In clinical trials, Bryhali Lotion was applied once daily for eight weeks and shown to be generally well-tolerated with no increase in epidermal atrophy.

"Topical steroids are a cornerstone of psoriasis treatment, but the efficacy of a high-potency steroid often comes with an increased risk of adverse events and a duration of use limited to two to four weeks," says Lawrence J. Green, MD, associate clinical professor of Dermatology at George Washington University School of Medicine in Washington, DC. "In clinical trials Bryhali Lotion has demonstrated good local tolerability for up to eight weeks of treatment without sacrificing efficacy, making it an important new treatment option for psoriasis patients."

FDA Approves Regeneron's Libtayo, First Treatment for Metastatic or Locally Advanced SCC

Regeneron Pharmaceuticals' Libtayo (cemiplimab-rwlc) injection is now FDA-approved for intravenous use for the treatment of patients with metastatic cutaneous squamous cell carcinoma (CSCC) or locally advanced CSCC who are not candidates for curative surgery or curative radiation. This is the first FDA approval of a drug specifically for advanced CSCC.

Libtayo works by targeting the cellular pathway known as PD-1 (protein found on the body's immune cells and some cancer cells). By blocking this pathway, the drug may help the body's immune system fight the cancer cells.

The safety and efficacy of Libtayo was studied in two open label clinical trials. A total of 108 patients (75 with metastatic disease and 33 with locally-advanced disease) were included in the efficacy evaluation. The study's primary endpoint was objective response rate, or the percentage of patients who experienced partial shrinkage or

MORE HEADLINES FROM DERMWIRE.COM

XBiotech Adds Dr. Alice Gottlieb to its Scientific Advisory Board

Alice Gottlieb, MD, an internationally recognized for her expertise and pioneering work in the development of biological therapies to treat skin diseases, has played key roles in the clinical evaluation of therapies such as etanercept, infliximab, ustekinumab, and secukinumab. She will help guide the clinical development of bermekimab, the XBiotech's candidate antibody therapy for skin diseases.

Almirall Updates

Almirall, S.A. finalized its acquisition of products from Allergan's Medical Dermatology unit in the US: Aczone (dapsone), Tazorac (tazarotene), Azelex (azelaic acid), and Cordran Tape (flurandrenolide). The newly approved sarecycline (Seysara) is also part of the transaction. These portfolio additions further enhance Almirall's presence in the U.S. dermatology space through their subsidiary Aqua Pharmaceuticals.

In other company news, Alrimal and Evotec have formed a Dermatology Research Collaboration. The companies aim to discover and develop first-in-class therapeutics through a novel approach to disrupt cell signaling, that is expected to deliver highly potent and durable treatments for debilitating dermatology diseases such as psoriasis and atopic dermatitis. The two companies have formed a collaboration that combines Evotec's cutting-edge drug discovery and pre-clinical development platforms with Almirall's leading expertise in dermatology diseases. Under the terms of the agreement, Evotec will receive research funding and may be eligible to receive discovery, pre-clinical, clinical and sales milestone payments as well as tiered royalties.

The Skin Cancer Foundation's Destination Healthy Skin Initiative Concludes

With a total of 1,243 free skin cancer screenings to its credit, The Skin Cancer Foundation's mobile skin cancer education and screening programDestination: Healthy Skinhas concluded its second annual journey around the US. Fifty-three dermatologists volunteered to provide the exams aboard the 38-foot Destination: Healthy SkinRV, where participants received The Skin Cancer Foundation's educational materials and Walgreens brand sun care items.

complete disappearance of their tumor(s) after treatment. Results showed that 47.2 percent of all patients treated with Libtayo had their tumors shrink or disappear. The majority of these patients had ongoing responses at the time of data analysis.

"We're continuing to see a shift in oncology toward identifying and developing drugs aimed at a specific molecular target. With the Libtayo approval, the FDA has approved six immune checkpoint inhibitors targeting the the PD-1 / PD-L1 pathway for treating a variety of tumors, from bladder to head and neck cancer, and now advanced CSCC," said Richard Pazdur, MD, director of the FDA's Oncology Center of Excellence and acting director of the Office of Hematology and Oncology Products in the FDA's Center for Drug Evaluation and Research. "This type of cancer can be difficult to treat effectively when it is advanced and it is important that we continue to bring new treatment options to patients."

Common side effects of Libtayo include fatigue, rash and diarrhea. Libtayo must be dispensed with a patient Medication Guide that describes uses of the drug and its serious warnings. Libtayo can cause the immune system to attack normal organs and tissues in any area of the body and can affect the way they work. These reactions can sometimes become severe or life-threatening and can lead to death. These reactions include the risk of immune-mediated adverse reactions including lung problems (pneumonitis), intestinal problems (colitis), liver problems (hepatitis), hormone gland problems (endocrinopathies), skin (dermatologic) problems and kidney problems. Patients should also be monitored for infusion-related reactions.

Bellus Medical Now Part of Crown Laboratories

Crown Laboratories, Inc. and Hildred Capital Partners, LLC have acquired Bellus Medical.

Bellus's non-invasive offerings include the SkinPen, a medical grade microneedling device used exclusively by healthcare professionals to improve the appearance of facial acne scars. It is the first microneedling device to be granted clearance and marketing authorization by the FDA or this indication.

Other Belus products include:

- Skinfuse: post-microneedling protocol
- Allumera:light-activated cream
- ProGenTM / RegenLab:platelet-rich plasma systems

Bellus Medical will become the new Aesthetics Division of Crown Laboratories and be renamed Bellus Aesthetics. Bellus will continue to be based in Dallas and operate as a wholly-owned subsidiary of Crown Laboratories. Bellus CEO Joe Proctor will become President of Crown's Aesthetics Division and join the Crown Board of Directors.

Research Identifies Disparities in Outpatient Dermatologic Care

The odds of a black or Hispanic patient visiting an outpatient dermatologist are about half that of a white patient with the same skin condition, according to a new study in JAMA Dermatology.

Patients most likely to receive outpatient dermatologic services were white, educated women, the study found.

Researchers from Case Western Reserve University School of Medicine and University Hospitals Cleveland Medical Center analyzed nine years of data from 183,054 dermatology patients across the country looking for demographic and socioeconomic patterns associated with use of dermatologic services.

The odds of a man seeking treatment for a dermatologic condition were about two-thirds that of a woman. Across all patients, service utilization increased proportionately with education level and income.

More services for certain patients meant higher costs: the per capita expenditure for white patients ($210) was approximately three times that of black ($63) or Hispanic ($73) patients, the study showed. While other variables might have had an impact, ethnic disparities still persisted after the researchers controlled for education level, income, insurance status and sex.

As demographics throughout the country become more diverse, understanding disparities in how patients use health services will be integral to developing policies that increase access to care. According to the authors, recent policies under the Patient Protection and Affordable Care Act increased access to care for low-income and low-education individuals, but did not significantly improve disparities for specific ethnic groups. It also did not increase access to specialized care, like dermatology, for many demographics.

Patients may also benefit from interventions that target specific dermatologic conditions. Half of the patients in the new study had a diagnosed dermatologic condition, yet only 36 percent of diagnosed patients sought care. Most patients diagnosed with a skin condition did not seek care at all during the nine-year study period.

The least likely to seek care were patients diagnosed with chronic skin ulcers. Nine out of ten patients with chronic skin ulcers did not see a dermatologist during the study period.

Dermatologists can help recognize such ulcers and get patients into proper treatment. Without seeking care, patients may be unaware of the root causes of their skin conditions.

Patients most likely to seek care in the new study were those diagnosed with non-melanoma skin cancers. Three out of four of these patients had at least one outpatient dermatologist visit during the study period. High service utilization in this population could prevent their non-melanoma lesions from turning more serious.

Previous research has shown the importance of visiting a dermatologist for patients with skin conditions. Early and accurate diagnoses can improve outcomes, and stave off deadly cancers. Patients least likely to seek care, whether due to demographics or diagnosis, could be at higher risk for serious skin conditions.

Candela and Vascular Birthmark Foundation Offer Pro Bono Laser Treatments for Patients in Need

Candela Corporation partnered with the Vascular Birthmarks Foundation (VBF) to provide pro-bono Vbeam laser treatments to children and adults with birthmarks, port wine stains and other vascular related skin conditions as a kickoff to the VBF 18th Annual Conference on October 5.

The treatments were performed at the Laser & Skin Surgery Center of New York in Manhattan on Friday, October 5 by the center's director, Dr. Roy Geronemus.

"Candela is committed to developing and enhancing innovative technological solutions that change lives. Our partnership with the Vascular Birthmarks Foundation and Dr. Roy Geronemus reflects this commitment," says Geoffrey Crouse, Chief Executive Officer of Candela, in a news release. "We are honored to offer these pro-bono treatments with the gold standard Vbeam Pulsed Dye Laser (PDL) to continue our mission to improve patients' quality of life."

One in ten children are born with a vascular birthmark. The Vbeam PDL is considered the gold-standard for the treatment of port wine stains and vascular anomalies in infants and children, as well as adults. Used by healthcare providers and close to 700 universities and hospitals worldwide, the device is associated with life changing outcomes, high patient tolerability and a low incidence of side effects.

"Vascular lesions, especially those on the face, have serious physical and psychological effects on patients," says Dr. Geronemus. "I am honored to be a part of the effort to provide patients with this life changing treatment. The Vbeam is without a doubt an incredibly safe and effective treatment for these conditions."

Following the Vbeam treatments scheduled for October 5, the Vascular Birthmarks Foundation Annual Conference will take place all day on Saturday, October 6 at Lenox Hill Hospital. The conference will offer educational sessions on the latest research and advancements in treatments for vascular birthmarks, including port wine stains, hemangiomas, and related conditions. Experts will also be available to meet with families throughout the day for sessions on makeup, psychotherapy, insurance issues and support. Candela is proud to be a key sponsor of this annual initiative.

Scar-less Healing May Be on the Horizon

Stromal cell-derived-factor-1 (SDF1), a compound secreted in the bloodstream, may be the key factor that causes wounds in older people to heal with less scarring than in younger people, according to researchers from the Perelman School of Medicine at the University of Pennsylvania.

What's more, blocking SDF1 could influence scar formation and tissue regeneration in mouse and human skin, potentially providing a path to scar-less wound healing in humans.

"Dermatologists and plastic surgeons have consistently observed that older people's wounds heal with thinner scars than younger patients', but until now, no one has been able to answer the question of why that's the case," says the study's senior author Thomas H. Leung, MD, PhD, an assistant professor of Dermatology at Penn, in a news release. In the study, Dr. Leung and his team pierced the ears of mice of different ages – the equivalent of a 12-year-old and a 70-year-old if converted to human years. The hole closed with no scar formation in older mice, while younger mice healed with a visible scar. Researchers then exchanged the blood of young mice with old mice, pierced their ears, and found that the ears of old mice now scarred. They concluded whatever was causing the scarring must be something in the blood.

The team then took tissue samples from young and old mice and compared their gene expression signatures. They identified 80 differences, too many to study. But when they asked which gene products are found in the blood stream, the list narrowed to 13 suspects. One was SDF1, a signaling molecule that was previously shown to play a role in scar formation in the skin, liver, and lung, and it seemed like a promising possibility. They confirmed that SDF1 was expressed in younger mice but not older. To prove that SDF1 may be the causal factor, they created a mouse that lacked SDF1 in the skin. When SDF1 function was inactivated, even young mice began to regenerate skin, behaving, in this sense, like older mice.

"This is a rare instance where aging actually improves the body's ability to heal rather than diminishing it," Dr. Leung says. "When we're younger, we secrete more SDF1 into the blood stream to form scars, but as we age, we lose this ability, which allows tissue to regenerate."

CLOSE UP

A Closer Look at Data on Nature-Based Skin Care

With Zoe Diana Draelos, MD

Practical Dermatology® spoke with Zoe Diana Draelos, MD, a research dermatologist in High Point, NC, about the results of her new study in *Journal of Drugs in Dermatology* that compared a nature based sensitive skin care regimen (Burt's Bee's, Durham, NC) to a dermatologist-recommended synthetic control regimen for the treatment of sensitive skin.

PD: Why is this topic important to study?

Zoe Diana Draelos, MD: Many patients are interested in natural skin care products that are free from chemicals. We were trying to understand the value of nature-based and sourced ingredients for sensitive skin in some of the most difficult skin conditions to treat and control. We picked conditions considered sensitive skin—rosacea, eczema, and cosmetic intolerance syndrome. We compared daily use of a nature-based regimen, which consists of Burt's Bees Sensitive Facial Cleanser, Sensitive Eye Cream, Sensitive Daily Moisturizing Cream and Sensitive Night Cream, to a dermatologist-recommended regimen of cetyl alcohol, sodium lauryl sulphate-containing cleanser and glycerin, polyisobutene-containing lotion. The control regimen has a heritage of effectiveness and is used by dermatologists for rosacea, eczema, and cosmetic intolerance syndrome. We wanted to see if we could reach this high bar with natural ingredients. There are a variety of naturally occurring anti-inflammatory ingredients present in nature-based products and a number of conventional ingredients that are absent, such as petroleum/petrolatum and polymers. Formulating with natural ingredients can be a challenge. The only ingredients that cannot always be naturally sourced for hydrous formulas are preservatives, and that is an industry-wide challenge. Current preservative-free products aren't shelf stable for a period that patients expect; it can be cost-prohibitive and difficult to use a bottle in a week, and product that is no longer stable could pose a risk to the user.

PD: Describe the research and your findings.

Dr. Draelos: This four-week, double-blind, randomized study was conducted in 120 women with clinically diagnosed rosacea, atopic dermatitis/eczema, or cosmetic intolerance. The nature-based sensitive skin regimen clinically and statistically improved physician-rated overall skin appearance by 34 percent with similar improvements in visual and tactile smoothness, clarity and radiance. By contrast, the maximum improvement in women using the synthetic regimen was four percent. There were no clinically significant tolerability issues reported in either regimen after four weeks of daily administration. Both regimens improved epidermal barrier function as measured by transepidermal water loss. The nature based regimen optimized skin hydration to improve and maintain skin health. The synthetic regimen was associated with over hydration possibly resulting from the occlusive barrier it provides. Overall, the natural-based skin care products proved superior in terms of visual skin smoothness, clarity and radiance, and these results continued to improve throughout the study.

PD: What is the next step?

Dr. Draelos: The next step is to study the effects of a natural regimen as adjunct to topical prescription therapy for rosacea. Study participants will use the comparator or the nature-based regimen to see if it is an effective adjunct for active disease.

To prove it, researchers exchanged the blood between young SDF1-deficient mice and older mice. This time, neither mouse scarred. The team went one step further and grew human skin in the lab, then injured it with a scalpel. Human skin also exhibited an age-dependent expression of SDF1.

Dr. Leung says this work has the ability to impact the clinic relatively quickly. SDF1 inhibitors already exist on the market and currently used as a treatment to mobilize stem cells. He and his team plan to study its use in preventing scar formation in humans. The findings appear in *Cell Reports*.

Galderma: Celebrity Manicurist Joins "Face Your Hands" Campaign

Galderma's Restylane Lyft is partnering with celebrity manicurist Deborah Lippmann for the "Face Your Hands" campaign, which aims to educate women on the steps they can take to achieve more youthful hands.

According to a recent survey conducted by Galderma, nearly 2 in 3 women (65 percent) age 40 and over think their hands make them look older than their age. Restylane

(Continued on page 25)

(Continued from page 18)

Lyft is the only hyaluronic acid (HA) dermal filler FDA-approved to help reverse the signs of volume loss in aging hands. Radiesse (Calcium Hydroxylapatite) is also approved for the correction of lost volume in hands.

As part of the initiative, Ms. Lippmann will connect with women across the country and share her nail care and manicure tips along with her personal experience with Restylane Lyft for hands.

The Restylane Survey was conducted among 1,000 nationally representative U.S. women, ages 35+, between February 26 and March 5, 2018, using an email invitation and an online survey. The data points in this release represent data collected among women ages 40+ (N=741).

FDA Green Lights First Spray-on-Skin Product for Burns

The FDA granted premarket approval to Avita Medical's Recell, a spray-on-skin that treats second- and third-degree burns in patients aged older than 18 years.

The US market launch for the Recell Autologous Cell Harvesting Device (RECELL System) is planned for 4th quarter 2018. The System uses a small amount of a patient's own skin to prepare Spray-On Skin Cells at the point of care in about 30 minutes.

The two randomized, controlled clinical trials supporting the FDA approval demonstrated that treatment of acute burn wounds with the Recell System required substantially less donor skin than conventional split-thickness autografts to achieve closure of burn wounds. Reduction in donor skin requirements provides key clinical benefits to patients and significant reductions in the cost of treatment.

The system can be used alone in the treatment of partial thickness burns, or in combination with autografting for the treatment of full-thickness burns. A small skin sample is collected and immersed in the Company's proprietary Enzyme solution in the Recell System to separate the skin cells to produce Spray-On Skin Cells. The resultant Regenerative Epidermal Suspension™ (RES™) includes keratinocytes, fibroblasts, and melanocytes, which play a critical role in wound healing. The suspension is then sprayed directly onto the prepared burn wound, providing a broad and even distribution of live cells across the entire wound bed. The Recell System can be used to prepare enough RES™ to treat a wound up to 80 times the size of the donor skin sample, so a skin sample approximately the size of a credit card can be used to treat a wound that covers a patient's entire back.