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AAD Launches SkinSerious Campaign

The American Academy of Dermatology (AAD) launched a new campaign at the 2017 AAD Annual Meeting to raise awareness of the breadth of serious skin diseases as well as the critical role dermatologists play in an era of team-based health care.

"We're launching the SkinSerious campaign to raise awareness of the impact these diseases have on more than 85 million Americans a year, improve access to dermatologists' expertise and increase collaboration with our physician peers to ensure high-quality patient care," says Detroit dermatologist Henry W. Lim, MD, FAAD, the new president of the AAD and chair of its Burden of Skin Disease Work Group, in a news release.

The SkinSerious campaign is supported by data from the "Burden of Skin Disease in the United States" report. This report quantifies the economic burden of 24 skin disease categories on patients and the healthcare system in the US, based on an analysis of medical claims in 2013 (see page 12 for more).

The report will be outlined in a series of manuscripts to be published in the *Journal of the American Academy of Dermatology*. The first article and commentary found that:

- Of the 24 skin disease categories analyzed in the study, half are associated with mortality.
- Nonmelanoma skin cancer and melanoma accounted for 60 percent of skin disease-related deaths.
- Prevalence of skin disease is high and is likely to increase as the population ages.
- The number of individuals with skin disease across the US population in 2013 exceeds those with cardiovascular disease, diabetes, or end-stage renal disease.
- One in four Americans (26 percent) reported receiving treatment for at least one skin disease in 2013.
- Nearly 50 percent of Americans over age 65 have skin disease, with an average of 2.2 skin diseases each.
- Patients and caregivers with skin disease suffered $11 billion in lost productivity. (This does not include additional time for at-home care and treatment, which was not evaluated.)
- $75 billion was spent on skin disease in 2013. The majority of this was for treatment costs, including $46 billion for health care provider costs from medical care.

FDA Approves Valeant's SILIQ For Moderate-To-Severe Plaque Psoriasis

The FDA approved the Biologics License Application (BLA) for Valeant Pharmaceutical's SILIQ (brodalumab) injection, for subcutaneous use, a monoclonal antibody that targets the IL-17 receptor for patients with moderate-to-severe plaque psoriasis. SILIQ is indicated for the treatment of moderate-to-severe plaque psoriasis in adult patients who are candidates for systemic therapy or phototherapy and have failed to respond or have lost response to other systemic therapies. Valeant expects to commence sales and marketing of SILIQ in the US in the second half of 2017.

SILIQ has a Black Box Warning for the risks in patients with a history of suicidal thoughts or behavior. SILIQ was approved with a Risk Evaluation and Mitigation Strategy (REMS) involving a one-time enrollment for physicians and one-time informed consent for patients. The most common adverse reactions were headache, arthralgia, fatigue, oropharyngeal pain, and diarrhea. SILIQ is contraindicated in patients with Crohn's disease. Suicidal ideation and behavior have been reported. Serious infections have occurred, therefore caution should be exercised when considering the use of SILIQ in patients with a chronic infection or a history of recurrent infection. Patients should be evaluated for tuberculosis infection prior to initiating treatment.

SILIQ works by binding to IL-17RA with high affinity, therefore blocking the inflammatory downstream activity of IL-17A, IL-17F, IL-17A/F heterodimer, and IL-17E. By targeting the IL-17 receptor, SILIQ prevents skin cells from accumulating. In three clinical studies that have been completed, more than 50 percent of patients who used SILIQ achieved total skin clearance within a year.

"SILIQ is the only product that has demonstrated 100% improvement in the psoriasis area and severity index (PASI 100) during clinical trials as a primary endpoint," said Lawrence J. Green, MD, associate clinical professor of Dermatology at George Washington University School of

Medicine in Washington, DC. "As the first IL-17 receptor A blocker that helps stop the proinflammatory cascade that leads to psoriasis, resulting in the normalization of skin inflammation, this is a significant achievement for the many patients who suffer with moderate-to-severe plaque psoriasis. SILIQ will be a welcomed addition to my treatment armamentarium."

In August 2015, Valeant entered into a collaboration agreement with AstraZeneca granting Valeant an exclusive license to develop and commercialize SILIQ globally, except in Japan and certain other Asian countries where rights are held by Kyowa Hakko Kirin Co., Ltd. In July 2016, AstraZeneca and Valeant amended Valeant's license for brodalumab to terminate Valeant's right to develop and commercialize brodalumab in Europe. LEO Pharma currently holds exclusive rights to develop and commercialize brodalumab in Europe, and Valeant holds the license to develop and commercialize SILIQ in the US and other territories, other than Japan and certain other Asian countries. In July 2016, brodalumab (marketed as LUMICEF) was granted approval from the Ministry of Health, Labour and Welfare Japan.

Sunburn Risk May Be Greatest in Skin of Color

Sunburn risk is greatest for young adults with melanin-rich skin, according to a study published in *The Journal of the American Osteopathic Association*.

Researchers found a surprising correlation between reporting a red or painful sunburn lasting a day or more with being 18 to 29 years of age and not self-identifying as white.

"The concern here is that participants with high melanin content skin may think they're naturally protected from sunburn, which isn't true," says Tracy Favreau, DO, an osteopathic dermatologist in Davie, FL. "We need to develop tailored sunburn prevention programs to change attitudes and reduce the risk of melanoma."

Dr. Favreau and the co-authors suspect the combination of youth and having melanin-rich skin provides a false sense of invincibility or resiliency to sunburn.

Some of the survey's predictors of sunburn seem obvious, like spending time outside during peak daylight hours or having a negative attitude toward sun protection. Others were less intuitive; for example, having a full-body skin exam or a perceived vulnerability to skin cancer.

There was no timeline established for survey participants. It could be that those who had serious sunburn were then more likely to get a full-body skin exam and feel more vulnerable to skin cancer.

Skin Diseases Remain Major Cause of Disability

Skin diseases are the fourth leading cause of disability worldwide, according to the Global Burden of Disease 2013 Study which appears online in *JAMA Dermatology*.

For the study, researchers estimated the global burden of skin disease as measured by disability-adjusted life years or DALYs, with one DALY equivalent to one year of healthy life lost.

Skin diseases account for 1.79 percent of the global burden of disease as measured in DALYS from 306 diseases and injuries in 2013, with skin and subcutaneous diseases responsible for 41.6 million DALYS that year.

Data were drawn from more than 4,000 sources including medical literature, population-based disease registries, hospital data, studies and autopsy data.

Skin diseases ranked in decreasing order by DALYS were: dermatitis (9.3 million DALYs), acne vulgaris (7.2 million DALYs), urticaria (hives, 4.7 million DALYs), psoriasis (4.7 million DALYs), viral skin diseases (such as viral warts, 4 million DALYs)), fungal skin diseases (3.8 million DALYs), scabies (1.7 million DALYs), melanoma (1.6 million DALYs), pyoderma and cellulitis (bacterial skin diseases, 1.1 million DALYs each), keratinocyte carcinoma (such as basal and squamous cell cancers, 820,000 DALYs), decubitus ulcer (bedsores, 660,000 DALYs) and alopecia areata (290,000 DALYs).

Overall, skin and subcutaneous diseases were the 18th leading cause of DALYs worldwide in the study and, excluding mortality, skin diseases were the fourth largest cause of disability worldwide.

Allergan to Acquire ZELTIQ for $2.47 Billion

Allergan plc and ZELTIQ Aesthetics, Inc. have entered into a definitive agreement under which Allergan has agreed to acquire ZELTIQ for $56.50 per share, or $2.475 billion, subject to customary adjustments.

The acquisition of ZELTIQ is immediately accretive and enhances Allergan's global medical aesthetics portfolio with the addition of ZELTIQ's flagship CoolSculpting System, which is FDA-cleared to affect appearance through lipolysis or reduction of unwanted fat using a patented cooling technology.

"The acquisition of ZELTIQ is highly complementary and strategic to Allergan. By adding the best-in-class body contouring CoolSculpting System to our best-in-class facial aesthetics, plastic surgery and regenerative medicine offerings we are creating a world-class aesthetics business," said Brent Saunders, Chairman and CEO of Allergan, in a statement. "With

CoolSculpting, our offerings to plastic surgeons, dermatologists, and aesthetic practitioners will now extend to three of the largest and fastest-growing segments of their practices, putting Allergan in a unique position to provide expanded customer service, and help meet the needs of patients."

"Allergan's world-class medical aesthetics products, global footprint, history and commitment to developing best-in-class aesthetic treatments makes the company ideally suited to realize the maximum commercial potential of the ZELTIQ controlled-cooling technology platform," said Mark Foley, Chief Executive Officer of ZELTIQ, in a statement. "I appreciate the unwavering commitment and dedication of the ZELTIQ team in building a world-class Company and technology platform with CoolSculpting. We look forward to working with Allergan to ensure successful completion of this transaction, and supporting the ongoing success of the CoolSculpting technology in the U.S. and around the world."

Allergan's acquisition of ZELTIQ is subject to approval by the shareholders of ZELTIQ, expiration or termination of the waiting period under the Hart-Scott-Rodino Antitrust Improvements Act of 1976, and fulfillment of certain other customary conditions to closing. Assuming typical regulatory and shareholder approval timeframes, Allergan currently anticipates closing the transaction in the second half of 2017.

Modernizing Medicine and Galderma Team Up to Offer Integrated OTC eCommerce Platform

Specialty-specific health information technology company Modernizing Medicine, Inc. and Galderma Laboratories, L.P. are collaborating to deliver new capabilities in support of improved patient experiences and outcomes through healthcare provider recommended over-the-counter (OTC) treatment regimens and patient education materials. The program, designed by Modernizing Medicine, will simplify the healthcare provider process of creating materials and educating patients about treatment regimens, which often incorporates a combination of prescriptions and OTC products and requires patients to follow very specific instructions. The enhancements will streamline the dissemination of educational materials and treatment plans, with a new feature that will enable patients to easily order physician-recommended OTC products online and have the products delivered directly to them.

Galderma, Nestlé Skin Health's medical solutions business, is working with Modernizing Medicine to bring the solution to market and will be one of the first suppliers making its OTC products available through this integrated eCommerce solution, specifically targeting dermatology and skin health. This is expected to include Galderma products such as Cetaphil gentle skin cleansers and moisturizers, including Cetaphil products specific for eczema-prone, acne-prone and redness-prone skin.

These enhancements to Modernizing Medicine's electronic health record (EHR) system, EMA, are designed to give clinical providers the ability to use structured data to document detailed treatment regimens combining prescription and OTC products. The application intelligently sequences the information and creates a document that is easy for the patient to understand. For example, a treatment regimen might instruct a patient to first cleanse their skin before applying a prescription cream and to then use a moisturizer. The patient education can also include integrated clickable links which enable direct-to-patient eCommerce for the OTC items.

This enhancement is designed to save time and improve patient compliance of OTC products, which can lead to better health outcomes. Patients will have an easier way to fulfill the physician's suggested OTC treatment plan and receive more informative patient handouts with product images and detailed instructions for use.

"This new functionality is being developed to help save time for both doctors and their patients, by providing a more powerful and easier to understand OTC treatment regimen with integrated eCommerce capability for over-the-counter products," explains Daniel Cane, CEO and co-founder of Modernizing Medicine.

While Modernizing Medicine is working with Galderma to create and test the new functionality, the company plans to include OTC products from other manufacturers and suppliers.

ACLARIS files NDA For Novel Seborrheic Keratosis Treatment

Aclaris Therapeutics, Inc. submitted a New Drug Application (NDA) to the FDA for A-101 40% topical solution (A-101) as a treatment for seborrheic keratosis (SK).

If approved, A-101 would be the first FDA-approved topical treatment for SK. Aclaris also plans to submit a marketing authorization application in the European Union in mid-2017.

Existing SK treatments are often painful, invasive, and can have undesirable outcomes such as pigmentary changes or scarring. Fewer than 10 percent of people with SK lesions currently receive treatment.

Positive results from two pivotal phase 3 trials — SEBK-301 and SEBK-302 — were reported in late 2016 and provide the clinical basis for this NDA submission. In these trials, A-101 met all primary and secondary endpoints, achieving clinically and statistically significant clearance of SK lesions. The two tri-

als, which were identical in design and together enrolled 937 patients, evaluated the safety and efficacy of A-101 compared with vehicle (placebo) in patients with four target SK lesions on the face, trunk and extremities.

Hologic to Acquire Cynosure

Hologic, Inc. and Cynosure, Inc. have signed a definitive agreement for Hologic to acquire all outstanding Cynosure shares for $66.00 per share in cash, which corresponds to an equity value of approximately $1.65 billion and an enterprise value of $1.44 billion net of cash.

The transaction, which has been approved unanimously by the boards of directors of both companies, would extend Hologic's scientific and commercial capabilities into one of the fastest-growing segments in medical technology, while expanding Cynosure's customer reach and addressable market.

"Acquiring Cynosure will accelerate our transformation into a higher-growth company by leveraging our core women's health expertise and OB/GYN channel leadership into an adjacent, cash-pay segment that is expanding at a low double-digit rate," said Steve MacMillan, Hologic's Chairman, President and Chief Executive Officer (CEO). "We had identified medical aesthetics as an attractive and complementary growth opportunity through our strategic planning process, and are pleased to have agreed to acquire Cynosure, the best-in-class company in the space. Together, we can strengthen our shared focus on innovation, market-leading products with demonstrated clinical benefits, and strong customer relationships. "

Cynosure has a broad portfolio of more than 20 products across major categories including non-invasive body contouring, hair removal, skin revitalization, and women's health. Cynosure sells its products through a combination of direct sales and distributors in over 130 countries. The company has a history of organic innovation, most recently with the introduction of SculpSure, FDA-cleared for non-invasive body contouring. Cynosure also markets MonaLisa Touch, a novel CO_2 laser for women's health. Cynosure, which reported revenues of $433.5 million in 2016, has posted 28 consecutive quarters of year-over-year top-line growth.

"We are thrilled at the prospect of becoming part of Hologic through a transaction that provides excellent value for all of our stakeholders," said Michael Davin, Cynosure's Chairman, President and CEO. "Strategically, this deal enables Cynosure to further capitalize on growth opportunities in the core and non-core aesthetic market, rapidly strengthens our position in women's health – where Hologic has a leading commercial presence – and accelerates our R&D initiatives."

New Research Highlights Need for Greater Sun Safety Education

Taken together, two new studies provide a mixed bag of news on the effectiveness of public health measures and messages aimed at decreasing skin cancer risk and improving sun safety behaviors.

One study shows that indoor tanning among high school students is starting to decline, but is still common among some students, while another study shows that schools are not promoting sun safety practices. Both reports appear in *JAMA Dermatology*.

In the first study, researchers from the US Centers for Disease Control and Prevention in Atlanta (CDC) report that indoor tanning decreased among students overall (from 15.6 percent in 2009 to 7.3 percent in 2015) but it was still common among some students, especially non-Hispanic white females where the prevalence of indoor tanning dropped from 37.4 percent in 2009 to 15.2 percent in 2015.

Indoor tanning also was associated with an increased likelihood of sunburn, although it was not possible to determine if the sunburns occurred because of indoor tanning or were related to the general behavior of indoor tanners who may incorrectly believe that a base tan reduces the risk of sunburn, the study showed. To arrive at their findings, researchers examined the prevalence of indoor tanning in the past year from 2009 to 2015 and its association with sunburn in 2015 among US high school students.

A second article looked at the prevalence of sun safety practices at schools and identified school characteristics associated with having policies in place to promote sun safety. The authors, also from the CDC, analyzed nationally representative school-level data from 2014.

Sun safety practices were not common among schools and high schools were less likely than elementary and middle schools to adopt several policies, according to the report.

For example, the most frequent practice (47.6 percent) was teachers giving time to students to apply sunscreen at school, although few schools (13.3 percent) made sunscreen available for students to use.

"Although skin cancer is the most common form of cancer in the United States, school practices that could protect children and adolescents from exposure to UV radiation from the sun while at school, and that could change norms about sun safety practices, are not common. … Many practices would cost little to implement and would support other messages targeted toward children, adolescents, adults and parents with an aim to reduce skin cancer morbidity and mortality," the article concludes. ■