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Consumer Reports: One-Third of Tested Sunscreens Delivered Less Than Half of Labeled SPF

For the fifth year in a row, *Consumer Reports*' (CR) testing has shown that some sunscreens failed to provide the level of protection promised on the package. Of the more than 60 lotions, sprays, sticks, and lip balms evaluated, 23 tested at less than half their labeled SPF number.

To check for UVB (SPF) protection, a standard amount of each sunscreen is applied to small areas of panelists' backs. Then they soak in a tub of water. Afterward, each area is exposed to six intensities of UVB light from a sun simulator for a set time. About a day later, a trained technician examines the areas for redness. The resulting UVB protection ratings reflect each product's actual effectiveness after water immersion and are based on an average of our results for each sunscreen.

CR isn't the only independent consumer organization that has found this discrepancy. Other members of International Consumer Research and Testing (a global group of consumer organizations) in Australia, New Zealand, and the UK have also found differences between the labeled SPF and the tested SPF in sunscreens on the market in those countries.

The *CR* analysis has revealed several high-performing sunscreen formulations. Some of the top-rated sunscreens identified by *CR* include La Roche-Posay Anthelios 60 Melt-in Sunscreen Milk, Equate Sport Lotion SPF 50, Pure's Sun Defense Disney Frozen Lotion SPF 50, Coppertone WaterBabies Lotion SPF 50, and Equate Ultra Protection Lotion SPF 50. They also give high marks to Trader Joe's Spray SPF 50+ and Banana Boat SunComfort Clear UltraMist Spray and Equate Sport Continuous Spray SPF 30.

Consumer Reports recommends using a sunscreen with an SPF of at least 40 that also contains ingredients like avobenzone rather than "natural" ingredients.

The American Academy of Dermatology issued a statement from President Henry W. Lim, MD, FAAD, on the Safety of Sunscreen. "The American Academy of Dermatology wants to emphasize that sunscreen remains a safe, effective form of sun protection. As one component of a daily sun-protection strategy, sunscreen is an important tool in the fight against skin cancer, including melanoma, the deadliest form of skin cancer.

Current scientific data does not support claims that sunscreen ingredients are toxic or a hazard to human health. Rather, evidence supports the benefits of applying sunscreen to minimize short- and long-term damage to the skin from the sun's harmful ultraviolet rays.

Sunscreen products contain one or more active drug ingredients—compounds that absorb, scatter or reflect UV light—and are regulated as over-the-counter drugs by the U.S. Food and Drug Administration (FDA). The FDA has several safety and effectiveness regulations in place that govern the manufacture and marketing of all sunscreen products, including safety data on its ingredients," reads part of the statement.

For the full statement, visit AAD.org.

Scrutiny of sunscreens is not new. Against the backdrop of increased attention to formulation efficacy and safety, Bayer, the maker of Coppertone, commissioned an independent "assurance assessment" designed to provide consumers with greater confidence when choosing sunscreen. Bayer retained AccountAbility to undertake an independent assurance assessment of Bayer's internal processes, systems, controls and performance guidelines for the labeling

Coppertone Whipped, a new sunscreen form that offers a light, creamy texture and absorbs quickly into skin, was among those Bayer assessed through its new independent assurance assessment program. The program found the company's products comply with internal and all applicable external guidelines to ensure the labeling accuracy of Coppertone products, accurately test and implement quality assurance procedures, and are found to comply with quality, safety and efficacy requirements.

accuracy of 10 of its top-selling Coppertone products in the US, and then make the report available to the public.

"Consumers are receiving information about sun protection from a variety of often contradictory sources, which is causing confusion. They want assurance that product performance claims are based on legitimate scientific testing," said Michael Tune, Vice President, Personal Care Development Center. "As a leader in the US sun care industry, we wanted to utilize our long-standing leadership to meet the changing expectations of consumers by voluntarily conducting —and sharing—this independent assurance assessment."

In 1944, Coppertone introduced the first commercial sun care product to consumers in the US. In 1972, Coppertone developed and introduced its "Sun Protection Factor," or "SPF index," and was the first to label its products with an SPF designation to identify the strength of sun protection. The standard was later adopted by the FDA and eventually, the entire global sun care industry.

Coppertone's Safety and Efficacy testing program is based on:

- Science and clinically relevant data
- FDA requirements
- Ongoing investment in comprehensive testing programs that go beyond what is required by the FDA, such as real-world use studies involving outdoor recreational activity including swimming in a pool
- Evaluating safety and efficacy, including for SPF and broad spectrum (protection from both UVA and UVB rays), by independent investigators, dermatologists, pediatricians and scientists
- Numerous global standards for SPF and UVA protection.

Bayer gave external assurance provider access to the facilities, records, and people necessary to conduct its assessment, including:

- Processes, systems, controls, performance data, principles and internal guidelines
- Testing and performance guidelines developed and enforced in accordance with U.S. regulations
- Quality assurance processes and systems developed and enforced for packaging and labeling
- Bayer's processes, controls and performance guidelines used to manage their suppliers
- 10 different products, including lotions, sprays, sticks and its new "Whipped" sunscreens

The independent assurance assessment concluded that the Bayer's products comply with internal and all applicable external guidelines to ensure the labeling accuracy of Coppertone products, accurately test and implement quality assurance procedures, and are found to comply with quality, safety and efficacy requirements.

FDA Accepts Aclaris Therapeutics' NDA for Topical Treatment of Seborrheic Keratosis

The FDA has accepted Aclaris Therapeutics' New Drug Application (NDA) for A-101 40% topical solution, an investigational drug for the potential treatment of seborrheic keratosis (SK). The NDA acceptance by the FDA in its 74-day letter indicates that the application is sufficiently complete to permit a substantive review. The PDUFA target action date for the completion of the FDA's review of the NDA is December 24, 2017. If approved, A-101 40% would be the first FDA-approved topical medication for the treatment of SK.

A-101 40% topical solution is a proprietary, high-concentration hydrogen peroxide formulation under investigation for the treatment of SK. It is being developed as a non-invasive, in-office treatment administered by physicians or other licensed health care professionals. In clinical trials, patients treated with A-101 40% achieved statistically and clinically significant improvement in clearing SK lesions compared to placebo and with a similar adverse event profile. A-101 40% is designed to work by penetrating into the SK lesion and causing oxidative damage, which can ultimately result in the sloughing of the SK cells. A-101 40% has been the focus of a robust clinical development program in which more than 700 patients have been treated with A-101. The 45% concentration of A-101 is also in clinical development for the treatment of common warts.

FDA Accepts Sun Pharma's BLA for Tildrakizumab

The FDA has accepted the Biologics License Application (BLA) for Sun Pharma's tildrakizumab, an investigational IL-23p19 inhibitor being evaluated for the treatment of moderate-to-severe plaque psoriasis. The BLA filing for tildrakizumab was submitted by Merck & Co., Inc. Sun Pharmaceutical Industries Ltd.'s wholly owned subsidiary acquired worldwide rights to tildrakizumab from Merck (through a Merck subsidiary), known as MSD outside the US and Canada, in 2014.

The news follows acceptance of the regulatory filing of tildrakizumab by the European Medicines Agency (EMA) in March 2017.

The BLA filing for tildrakizumab with the U.S. FDA is based on two pivotal Phase III trials (reSURFACE 1 and 2) which included more than 1,800 patients across more than 200 clinical trial sites, including some patients who have been treated with tildrakizumab for up to three and a half

Take 5

WITH LEE BUCKLER, PRESIDENT & CEO, REPLICEL LIFE SCIENCES INC.

Regenerative medicine—the science of harnessing the body's own cells, tissues or organs for healing—may well change the way we address and treat a host of medical conditions including hair loss and skin aging. Lee Buckler, President & CEO, RepliCel Life Sciences Inc. in Vancouver, BC, talked to Practical Dermatology® magazine about what is promising, possible, and even more importantly probable based on his company's research and development.

1. FRUITFUL DISCOVERY PROCESS

"In androgenic alopecia, dihydrotestosterone (DHT) decimates the cell population in the affected areas of scalp, but many bald people still have hair on the back of their head. We took tissue biopsies from the back of the head and discovered several cell populations. Some have everything to do with growing hair and others have to do with the growth and maintenance of the hair follicle. We narrowed it down further to two groups, one which we think of as cellular injection for androgenic alopecia (RCH-01) and another fibroblast (RCS-01 RepliCel's type 1 collagen-expressing, hair follicle-derived fibroblasts) which is highly expressive of collagen. RCS-01 may be useful for clinical indications where there is a deficit of type 1 collagen related to regeneration such as when the breakdown of the extracellular matrix leads to skin sagging, wrinkling and/or for the treatment chronic tendinosis caused by acute and chronic tensile overuse."

2. REGENERATIVE MEDICINE IN ACTION

"In our laboratory experience and now in our first-in-human research, when you inject these cells under the right conditions, right circumstances and right protocol, they will do one of two things: take up residence in local tissue and provide the function they would otherwise perform or interact with resident tissue and cells and perform said function then disappear. When the cells themselves disappear, they express tissue-building proteins and we see a regeneration of natural tissue before they leave or graft. With RCS-01, we see actual re-generation of extracellular matrix under the skin that we would otherwise fill temporarily with off-the-shelf injectables. We are not really targeting deep wrinkles. Instead, we are initially targeting fine wrinkles across the cheeks and décolleté area that can't be treated with fillers or fat. This is our initial target market, and we think it is our distinguisher."

3. ROBUST PIPELINE

"We reported statistically and clinically significant positive data from the interim analysis of its phase I study evaluating RCS-01 for the treatment of aging and sun-damaged skin. The primary objective of this trial was to establish a complete safety profile for RCS-01 at six months post-injection. There were no serious adverse events at the interim point of the trial. There was also positive proof-of-concept data indicating the product's potential for skin rejuvenation—a nearly two-fold increase in gene expression of 10 different collagen-related biomarkers in the skin was seen after a single injection of RCS-01.

The hair loss cell therapy is further along in trials than RCS-01. A five-year trial data set confirmed the complete safety profile of a high-dose of RCH-01 for patients with androgenic alopecia. The seven top-tier responders in the trial saw >10 percent increase in hair density at six months post-injection, At 24 months, the average hair density increase for these same seven participants was 8.3 percent over baseline, and three of these seven trial participants maintained a >10 percent increase in density over baseline. The largest increase in hair density over baseline observed in this group was a 21 percent increase at 24 months. A Phase 2 trial of RCH-01 will study various ways to optimize efficacy by studying dosing, treatment frequency, and product characteristics. In Japan, Shiseido continues to fund a two-site clinical research study of RCH-01. The pathway under which Shiseido is conducting these trials in Japan suggests the product may be the subject of early commercialization there, after data readouts in 2018."

4. REGENERATIVE MEDICINE IN PRACTICE

"If a patient is considering hair restoration at a hair transplant clinic or dermatologist, they would have the discussion about options. If the patient choses RCH-01, the doctor takes a single punch biopsy from the back of the head and the tissue is then shipped to manufacturer where the selected cells can be replicated, and six to eight weeks later, a cryopreserved product is ready for delivery

and reintroduction into balding areas on the scalp."

5. BETTER INJECTORS

"Without control over the way a product is injected, there is no control over the outcome. RCI-02 is a next-generation dermal injector which does just that. It is designed to provide an improved level of control and precision for intradermal, subcutaneous or intramuscular injections. It was originally designed for RCH-01 and RCS-01 cell therapy products, but it has broader applications for dermatological procedures requiring injections of specific volumes of material at specific depths including cellular products, fillers, hyaluronic acids, fat and collagen injections. We received a United States Patent for this injector in April 2017 and expect our first commercial grade functional prototype in July."

years. Data from these trials were most recently presented at the 2017 American Academy of Dermatology (AAD) Annual Meeting in March and previously presented at the 25th European Academy of Dermatology and Venereology Congress. Future presentations and publications of the reSURFACE Phase-3 pivotal trials will include more scientific insights on the data to week 52 and beyond. The clinical trials are designed to evaluate safety and efficacy for up to five years, and to date, some clinical trial participants have been treated with tildrakizumab for up to three and half years.

Study: Antioxidants Protect Against Atmospheric Skin Aging

Exposure to ozone pollution zaps the skin's collagen supply, according to new research from SkinCeuticals in partnership with Professor Giuseppe Valacchi from the University of Ferrara, Italy.

After exposure to 0.8ppm ozone, collagen was reduced on live skin, the study showed. In addition, ozone pollution oxidizes lipids and depletes skin's natural antioxidant reservoir, triggering a progressive cascade of damage that may contribute to signs of skin aging. Findings are slated to be published in the *Journal of Investigative Dermatology*.

SkinCeuticals worked with Dr. Valacchi to help combat the effects of ozone on skin. Together they found that application of SkinCeuticals antioxidants C E Ferulic and Phloretin CF significantly reduced the damage caused by ozone exposure by neutralizing free radicals on the upper layer of the skin. Moreover, an increase in HNE (proteins that mark lipid oxidation) levels and activation of the NfKB (sensitization markers) pathway were also studied when skin was exposed to 0.8ppm ozone. When C E Ferulic or Phloretin CF were applied, these markers were significantly reduced.

Antioxidants are just one part of a comprehensive Prevent + Protect regimen. In order to protect skin against the full spectrum of environmental threats, a sunscreen is crucial, as well. When used together, SkinCeuticals antioxidants and broad-spectrum sunscreens provide a complimentary approach against visible aging caused by UVA/UVB rays, IR-A, and ozone pollution exposure.

Nominations Open: ASLMS Leadership, Mentorship & Public Advocacy for Women in Medical Science Award

The ASLMS Leadership, Mentorship & Public Advocacy for Women in Medical Science award was established in 2015 by the ASLMS Women in Energy-Based Devices Committee with the purpose of honoring an individual, either male or female, who has significantly promoted the professional development of women in specialties using lasers and/or energy-based devices, through teaching, mentoring, organizational leadership, or public advocacy.

This award may be given to either ASLMS members or non-members. It will be presented at the Celebration of ASLMS Women in Energy-Based Devices event at the Annual Conference. The award recipient will receive a plaque and $1,000 and will be required to present a brief talk at the event. Nominations for 2018 are now open. Nomination deadline is September 1, 2017.

According to the ASLMS, the candidate must meet the following criteria in order to be considered for this award:

Embody the spirit and intent of the award through his or her excellence in leadership, mentoring, and continuous promotion of the professional development of women in specialties using energy-based devices

No award will be granted to any person if the award would be contrary to any United States law, including but not limited to trade embargoes administered by the US Treasury Department's Office of Foreign Assets Control.

Visit aslms.org to learn more, to nominate an individual online, or to download a nomination form. ■