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# Oculus Innovative Sciences Receives FDA Clearance for Microcyn®-Based SebDerm Gel

## U.S. Launch During June Quarter 2016

PETALUMA, Calif., Dec. 17, 2015 (GLOBE NEWSWIRE) -- Oculus Innovative Sciences, Inc. (NASDAQ:OCLS) (warrants OCLSW), a specialty pharmaceutical company that develops and markets solutions for the treatment of dermatological conditions and advanced tissue care, today announced that it has received a new 510(k) clearance from the U.S. Food and Drug Administration (FDA) for the company's new Microcyn®-based SebDerm Gel. As a prescription product, SebDerm Gel is intended to manage and relieve the burning, itching, erythema, scaling, and pain experienced with seborrhea and seborrheic dermatitis. It also helps to relieve dry, waxy skin by maintaining a moist wound and skin environment, which is beneficial to the healing process.

Zoe Draelos, MD and president of Dermatology Consulting Services in High Point, North Carolina, commented, "Seborrheic dermatitis is a common condition afflicting men and women of all ages that is challenging for dermatologists to treat. While treatment options exist, recurrence is common and few options exist for disease maintenance. A new addition to the dermatologist's armamentarium, such as the Microcyn technology, will be welcome."

In addition to U.S. commercialization, which is planned for the quarter ending June 30, 2016, via IntraDerm's 19-person direct sales team, Oculus is working with its international distributors and partners to bring this advanced technology to dermatology patients throughout the globe, including Asia and the Middle East.

"Our new Microcyn-based SebDerm gel adds a valuable tool to the dermatologist's bag when it comes to combatting both seborrhea and seborrheic dermatitis," said Jeffrey Day, president of IntraDerm Pharmaceuticals, Oculus' dermatology division. "Nearly a quarter of the general population is afflicted with seborrheic dermatitis, thus a solution that resolves this ubiquitous skin disease is anticipated to be widely embraced."

### SebDerm Market Size

It is estimated that 25% of the general population has seborrheic dermatitis. Although the etiology of seborrheic dermatitis is not entirely understood, most experts share the belief of Bruce Strober, M.D., Ph.D., co-director of the psoriasis and psoriatic arthritis center at New York University Medical Center, who says, "The disease may be triggered by environmental factors, but there is a strong immune predisposition." The disease is far more prevalent in patients with HIV, neurologic disorders, elderly patients and infants.

According to *JAMA Pediatrics*, an industry healthcare journal, seborrheic dermatitis is a

common complaint brought to pediatricians. Also known as “cradle cap” in infants, “dandruff” in adolescents, seborrheic dermatitis is also found in the face, scalp and chest areas in adults. It is believed this condition is triggered by *Malassezia* yeasts. Treatment has supported a billion dollar market for over-the-counter treatments.

### **Current Treatment Options**

Studies have also shown a causative role of the yeast-like fungus *Pityrosporum* in the development of seborrheic dermatitis, notes Joel Schlessinger, M.D., a dermatologist in private practice in Omaha, Nebraska, and president emeritus of the American Society of Cosmetic Dermatology & Aesthetic Surgery.

Dr. Schlessinger advocates the use of both oral ketoconazole (weekly for six to eight weeks) and a topical foam to treat the underlying *pityrosporum* infection. In addition, newer formulations of corticosteroids, like clobetasol and betamethasone, he says, “have markedly changed the treatment of scalp psoriasis and seborrheic dermatitis. Before these were available there were few palatable options for these conditions, but now the treatments are quite ‘patient friendly.’ Older treatments such as Derma-Smoother F/S and other tar-based shampoos are clearly a challenge for patients and often result in poor results due to compliance issues.”

Current therapies include the use of a topical ketoconazole-containing agent. If that is not effective, then dermatologists may step up to a topical corticosteroid, with lower potency on the face, higher potency on the scalp. Another popular option is the use of topical immunomodulatory drugs, like tacrolimus and pimecrolimus. These agents have been found to be safe and effective for seborrheic dermatitis on the face. The downside is that they burn and sting. If there is not a reimbursement issue, dermatologists often prescribe these drugs as first-line therapy.

### **Microcyn® Technology (HOCl) Mode of Action**

- Hypochlorous acid (HOCl), such as that found in Microcyn® Technology, has been shown in non-clinical studies to kill bacteria, viruses, spores, and fungi through well-studied mechanisms of action, including denaturation, a process in which the structure of surface proteins on the microorganism are irreversibly changed or damaged. This results in the destruction of pathogen.
- Human bodies have evolved over thousands of years to produce HOCl naturally to kill infection-causing microbes quickly and without presenting the opportunity for those pathogens to mutate and become resistant. Oculus believes it has chemically engineered its Microcyn® Technology to mimic the body’s natural response to unwanted organisms, without the undesirable side effects resulting from the overuse of antibiotics.

### **About IntraDerm Pharmaceuticals**

A division of Oculus Innovative Sciences, IntraDerm Pharmaceuticals is a global dermatology enterprise with an initial focus on Microcyn®-based dermatology products. The division’s headquarters are in Petaluma, California with additional sales operations in the Netherlands, and manufacturing operations in the United States and Latin America. More information can be found at [www.intraderm.com](http://www.intraderm.com).

## **About Oculus Innovative Sciences, Inc.**

Oculus Innovative Sciences is a specialty pharmaceutical company that develops and markets solutions for the treatment of dermatological conditions and advanced tissue care. The company's products, which are sold throughout the United States and internationally, have improved outcomes for more than five million patients globally by reducing infections, itch, pain, scarring and harmful inflammatory responses. The company's headquarters are in Petaluma, California, with manufacturing operations in the United States and Latin America. European marketing and sales are headquartered in Roermond, Netherlands. More information can be found at [www.oculusis.com](http://www.oculusis.com).

## **Forward-Looking Statements**

Except for historical information herein, matters set forth in this press release are forward-looking within the meaning of the "safe harbor" provisions of the Private Securities Litigation Reform Act of 1995, including statements about the commercial and technology progress and future financial performance of Oculus Innovative Sciences, Inc. and its subsidiaries (the "Company"). These forward-looking statements are identified by the use of words such as "planned," "anticipated," and "believes," among others. Forward-looking statements in this press release are subject to certain risks and uncertainties inherent in the Company's business that could cause actual results to vary, including such risks that regulatory clinical and guideline developments may change, scientific data may not be sufficient to meet regulatory standards or receipt of required regulatory clearances or approvals, clinical results may not be replicated in actual patient settings, protection offered by the Company's patents and patent applications may be challenged, invalidated or circumvented by its competitors, the available market for the Company's products will not be as large as expected, the Company's common stock and warrants may be delisted from NASDAQ, the Company's products will not be able to penetrate one or more targeted markets, revenues will not be sufficient to fund further development and clinical studies, the Company may not meet its future capital needs, the Company may not be able to obtain additional funding, as well as uncertainties relative to varying product formulations and a multitude of diverse regulatory and marketing requirements in different countries and municipalities, and other risks detailed from time to time in the Company's filings with the Securities and Exchange Commission including its annual report on Form 10-K for the year ended March 30, 2015. The Company disclaims any obligation to update these forward-looking statements, except as required by law.

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