

Oculus Innovative Sciences Receives FDA Clearance for Microcyn(R) Scar Management HydroGel

- Oculus U.S Dermatology Partner, Quinnova Pharmaceuticals, Targeting U.S. Launch in Q2 2014
- U.S. Double-Blind, Randomized Study for Scar Management Establishes Strong Foundation for International Approval

PETALUMA, Calif., Dec. 4, 2013 (GLOBE NEWSWIRE) -- Oculus Innovative Sciences, Inc. (Nasdaq:OCLS), a global healthcare company that designs, manufactures and markets prescription and non-prescription products in 27 countries, 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® Scar Management HydroGel. The Rx product, under the supervision of a healthcare professional, is intended for the management of old and new hypertrophic and keloid scarring resulting from burns, general surgical procedures and trauma wounds. Oculus U.S. dermatology partner, Quinnova Pharmaceuticals, intends to commercialize the product in the first half of 2014.

"We have known for years that there has been practitioner demand for an efficacious and safe prescription treatment to manage hypertrophic and keloid scarring," said Jeffrey Day, Quinnova Pharmaceuticals CEO. "Having seen first hand the compelling impact that our Microcyn-based Technology products have had on the management of conditions such as atopic dermatitis, we are equally excited about its potential as well in managing scars. The data from the FDA-required study certainly validates the product's potential in the dermatology space."

In addition to U.S. commercialization, Oculus is working with its international distributors and partners to bring this new scar product to patients throughout the globe, including Latin American partner, More Pharma, with anticipated commercialization in Mexico in 2014. Further product launches should follow shortly after in other Latin American countries as regulatory approvals are secured. In the Asian countries of China, Singapore, Malaysia and India, product launches are anticipated sometime after April 2014. Similarly, the scar product will be introduced in Kuwait, UAE, Jordan and Iraq in the same time frame.

As part of the FDA 510(k) review process, Oculus conducted a double-blind, multi-center randomized clinical study to demonstrate equivalency to a predicate device in scar management. The 40-patient study was conducted at four U.S. investigative sites over 16 weeks, ending March 2013. Qualified scars included linear or widespread hypertrophic or keloid scars. The age of target scars ranged between three months and one year. Investigators evaluated the qualified scar using the Vancouver Scar Scale, which assesses scar vascularity, height/thickness, pliability and pigmentation. In addition, pain and

itch symptoms were evaluated by the subjects.

The VSS total score was calculated for each subject and visit as the sum of the scores reported for each of the three items (vascularity, pliability, and height). The VSS total score ranged from zero to nine. Individual sign and symptoms were summarized by treatment group. The count and percent of subjects in each category were presented for the VSS items of vascularity, pliability, and height, and for the subject assessment of scar symptoms for pain and itch.

In both the Microcyn HydroGel and the active control groups, the VSS total score improved consistently at each of the visits. At the end of treatment visit (Day 56), the mean VSS total score improvement from baseline was -2.10 in the Microcyn group, versus -1.28 in the control group. At the end of the study visit (Day 112), the mean VSS total score improvement was -2.70 in the Microcyn group and -1.83 in the control group. While both groups improved, the reductions were greater in both instances for the Microcyn group.

Individual signs and symptoms scores were evaluated throughout the study, which included improvement in itch and pain. The reductions from baseline in the mean individual signs and symptoms scores were greater in the Microcyn group.

"We are pleased to receive this scar management 510(k) clearance, which is the eighth FDA approval or clearance for our Microcyn-based products to date," said Jim Schutz, Oculus CEO. "We believe that Quinnova's dermatology sales and marketing expertise, and our strong supporting clinical data for this new product, is a winning combination for doctors and their patients. We look forward to sharing this new FDA clearance with our international partners to make this great product available outside the United States as soon as we clear international regulatory hurdles."

Scar Treatment Market

According to a 2003 report by Frost & Sullivan, it is estimated that 62 million scars are formed each year in the United States. There are about 93 million people in the United States suffering from scars, out of which about 169 million scars can be characterized as hypertrophic (raised) and keloid (red colored) scars. The raised and red scars market forms the primary target for the scar therapy products. Annually, about 600,000 visits for burns and more than 2.6 million emergency room visits for cut injuries, this forms the potential market for the scar therapy products. The statistics show that out of 6.2 million reconstructive procedures performed on patients in a year, 250,000 surgeries are related with scar revisions.

About Quinnova Pharmaceuticals, LLC.

A wholly owned subsidiary of AmDerma, LLC, Quinnova Pharmaceuticals, LLC. is a specialty pharmaceutical company founded on innovative, patent-protected dermal delivery technologies. The company's delivery platforms are utilized to transport safe and effective pharmaceutical ingredients through the epidermis in unique, convenient and cosmetically elegant formulations. Addressing a wide variety of skin conditions, it is Quinnova's mission to provide superior treatment solutions and product value to clinicians and patients alike. For more information, please visit www.guinnova.com.

About Oculus Innovative Sciences

Oculus Innovative Science is a global healthcare company that designs, manufactures and markets prescription and non-prescription products in 27 countries. The company's products are used to treat patients in surgical/advanced wound management, dermatology, women's health and animal health markets; addressing the unmet medical needs of these markets, while raising the standard of patient care and lowering overall healthcare costs. The company's headquarters are in Petaluma, California, with manufacturing operations in the United States and Latin America. More information can be found at www.oculusis.com.

Forward-Looking Statements

Except for historical information herein, matters set forth in this press release are forwardlooking 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 "issuance," "provides," and "tracking," 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 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, the uncertainties associated with an initial public offering of a separate public company, and the discretion of the Company's Board of Directors to delay or cancel the spinoff prior to execution, 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 31, 2013. The Company disclaims any obligation to update these forward-looking statements, except as required by law.

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