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Oculus Innovative Sciences Introduces Microcyn(R)-Based Over-the-Counter Advanced Scar Management Hydrogel in United States

PETALUMA, Calif., Sept. 10, 2014 (GLOBE NEWSWIRE) -- Oculus Innovative Sciences, Inc. (Nasdaq:OCLS), a global healthcare company that designs, manufactures and markets prescription and non-prescription products in 33 countries, today introduced Regenacyn™ Advanced Scar Management Hydrogel into the U.S. over-the-counter market. Formulated from the company's flagship Microcyn® Technology platform, Regenacyn is a customized solution designed to address the underserved consumer scar management market.

The Regenacyn Advanced Scar Management Hydrogel has been clinically shown to improve the texture, color, softness and overall appearance of scars. It is intended for the management of old and new hypertrophic and keloid scars resulting from burns, general surgical procedures and trauma wounds. It will be sold through plastic surgeons and OBGYNs to patients.

Regenacyn is in stock and now available. For more information, pricing or ordering visit www.oculusis.com or phone 1-800-759-9305. A by-prescription-only formulation of the wound management gel will be made available later this fall.

"The scar hydrogel delivered significant improvement in all end points assessed, including reduction of pain and itch," said Zoe Diana Draelos, MD, investigator in the FDA study required for 510(k) clearance. "Positive results across the board were seen in our comparator clinical study."

Oculus received a 510(k) over-the-counter clearance from the U.S. Food and Drug Administration (FDA) for the Regenacyn Advanced Scar Management Hydrogel in December 2013. 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. 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.

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 Oculus Innovative Sciences, Inc.

Oculus Innovative Sciences is a global healthcare company that designs, manufactures and markets prescription and non-prescription products in 33 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 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 "accelerate," "preparing," and "launch," 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, 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, 2014. The Company disclaims any obligation to update these forward-looking statements, except as required by law.

CONTACT: Media and Investor Contact:

Oculus Innovative Sciences, Inc.
Dan McFadden
VP of Public and Investor Relations
(425) 753-2105
dmcfadden@oculusis.com

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