

## Oculus Innovative Sciences Receives European CE Mark for New Microcyn(R)-Based Scar Management Hydrogel

 New Epicyn™ Hydrogel to be Introduced at Medica Trade Fair on November 12-15 in Dusseldorf, Germany

ROERMOND, Netherlands and PETALUMA, Calif., Nov. 4, 2014 (GLOBE NEWSWIRE) -- Oculus Innovative Sciences, Inc. (Nasdaq:OCLS), a global healthcare company that designs, manufactures and markets prescription and non-prescription products in 36 countries, today announced the issuance of a new CE Mark in Europe for Microcyn®-based Epicyn™ Hydrogel. Epicyn Hydrogel is indicated for the management and reduction of new and existing hypertrophic and keloid scars, assisting with moistening while forming a protective barrier against physical, chemical and microbial invasion of the scar.

"This is an exciting opportunity to bring to Europe a clinically proven scar management product that excels in safety, efficacy and cost-efficiency," said Frans Maes, European dermatology sales manager for Oculus. "The double-blind study conducted in the United States solidly demonstrates that the Microcyn Technology in the Epicyn formulation convincingly outperforms the competition in terms of patient relief and scar improvement."

Oculus received a 510(k) over-the-counter clearance from the U.S. Food and Drug Administration (FDA) for the Microcyn-based 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 (VSS), which assesses scar vascularity, height/thickness, pliability and pigmentation. In addition, pain and itch symptoms were evaluated by the subjects.

"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."

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.

The following table shows the percentage improvement of Epicyn over baseline as compared to the control, Kelo-Cote®:

Percentage Improvement over Base Line at the end of Week 12:

	Epicyn	Control
Vascularity	42%	28%
Pliability	47%	34%
Height	30%	11%
Vancouver Score	40%	26%
Pain	100%	72%
Itch	78%	70%

As indicated, 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.

Epicyn will be marketed under the IntraDerm Pharmaceuticals EU brand, a recently created division of Oculus Innovative Sciences. The product will launch at Medica Trade Fair (<a href="http://www.medica-tradefair.com">http://www.medica-tradefair.com</a>) in Dusseldorf, Germany on November 12-15, 2014.

Overseeing the development and launch of the IntraDerm EU dermatology products in Europe will be a dermatology sales manager, Frans Maes. Maes has an extensive background in nursing and more than 15 years of experience in international sales and marketing within various international healthcare companies. To date, Oculus and its European divisions have secured 10 CE Mark approvals for both dermatology and advanced tissue care products.

## **Scar Treatment Market**

According to an article in the 2003 *The BMJ* (British Medical Journal), each year in the developed world 100 million patients acquire scars, some of which cause considerable problems, as a result of 55 million elective operations and 25 million operations after trauma. There are an estimated 11 million keloid scars and four million burn scars, 70% of which occur in children. Global figures are unknown but doubtless much higher. People with abnormal skin scarring may face physical, aesthetic, psychological, and social consequences that may be associated with substantial emotional and financial costs.

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

Oculus Innovative Sciences is a global healthcare company that designs, manufactures and markets prescription and non-prescription products in 36 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. European marketing and sales are headquartered in Roermond, Netherlands. More information can be found at <a href="https://www.oculusis.com">www.oculusis.com</a>

## **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 "will be," "outperforms," 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 forwardlooking statements, except as required by law.

Oculus®, Microcyn® Technology, Epicyn™ and IntraDerm Pharmaceuticals™ are trademarks or registered trademarks of Oculus Innovative Sciences, Inc. All other trademarks and service marks are the property of their respective owners. High-resolution product photos are available. Please call or email request.

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Source: Oculus Innovative Sciences, Inc.