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# **Oculus Innovative Sciences Announces Publication of Microcyn(R) Technology Diabetic Wound Study in Journal of College of Physicians and Surgeons Pakistan**

## **Microcyn Shows Shorter Duration of Hospital Stay, Downgrading of the Wound Category and Shorter Wound Healing Time**

PETALUMA, Calif.--(BUSINESS WIRE)--

Oculus Innovative Sciences, Inc. (Nasdaq: OCLS) announced today that the Journal of College of Physicians and Surgeons Pakistan has published results from a randomized and controlled study of the company's Microcyn(R) Technology in 100 patients in Pakistan with infected diabetic wounds. In this study, Microcyn showed a statistically significant benefit versus saline with respect to the primary endpoints: duration of hospital stay, downgrading of the wound category and wound healing time. A reprint of the peer-reviewed paper, entitled "Treating Infected Diabetic Wounds with Superoxidized Water as Anti-Septic Agent," is available online at: <http://www.oculusis.com/jcpsp.pdf>.

Researchers at the Pakistan Institute of Medical Sciences in Islamabad, Pakistan randomized 100 diabetic patients with infected wounds. Patients received Microcyn (intervention group) or normal saline (control group) in combination with ofloxacin, an intravenous antibiotic, until wound healing. Each patient's wound was classified into one of four grades depending on the presence of the following characteristics: Grade 4, necrotic tissue or frank pus; Grade 3, slight slough or serosanguinous secretion; Grade 2, granulation tissue; and Grade I, healthy epithelialization considered as healing. All patients had prior surgical wound treatment and received their assigned study treatment (Microcyn or saline). Local wound treatment consisted of twice-daily application of Microcyn-soaked gauzes in the intervention group and normal saline in the control group.

As shown in tables 1 and 2, statistically significant differences were apparent in favor of the intervention group with respect to the duration of hospital stay, downgrading of the wound category and wound healing time (p value less than 0.05 in all categories).

Most of the infected patients with wounds grade IV (61.76%) and grade III (70%) healed within one week of Microcyn therapy in comparison to a lower healing rate in patients treated with topical saline (14.7% and 20%, respectively). Even wounds with granulation tissue achieved a faster complete epithelialization, if they were assigned to the study agent (100%) instead of saline (50%). As a result, 62% of the patients in the study group were discharged

from the hospital in less than seven days in comparison to only 20% of those receiving saline.

Table I: Wound downgrading observed one week of treatment (n =50 per group)

Wound category on Day 1	Wound category on Day 8	No. of patients (study group)	No. of patients (control group)
IV	I	21 (61.76%)	5 (14.7%)
IV	II	8 (23.52%)	13 (38.23%)
IV	III	5 (14.7%)	16 (47%)
III	I	7 (70%)	2 (20%)
III	II	3 (30%)	8 (80%)
II	I	6 (100%)	3 (50%)

Table II: The duration of hospitalization among the patients of the two groups (n = 50 each group)

Duration of Hospitalization	No. of patients (study group)	No. of patients (control group)
1-7 days	31 (62%)	10 (20%)
8-14 days	9 (18%)	17 (34%)
15-21 days	7 (14%)	15 (30%)
greater than 21 days	3 (6%)	8 (16%)

These results are relevant considering that all patients were on systemic antibiotics as well. They suggest that Microcyn could be inducing wound healing by mechanisms different from the sole mechanical debridement or the reduction of microbial load in the wound. The authors discuss the favorable cost-benefit ratio of this novel topical therapy in terms of better outcomes, patient satisfaction, antibacterial spectrum, control of antibiotic resistant pathogens, simplicity of use and lower costs of attention. They conclude that, based on these positive results, further multi-center clinical trials are warranted.

Hoji Alimi, founder and CEO of Oculus, commented, "Results from this study support prior findings from 23 global Microcyn studies involving more than 800 patients. These data also complement positive top-line results from our U.S. Phase II study of Microcyn as a treatment for mildly infected diabetic foot ulcers, which showed a 93% clinical success rate as a monotherapy versus just 56% for the levofloxacin plus saline-treated patients at the test of cure visit on day 24 in the clinically evaluable patient population. Based upon this continued and consistent validation of the Microcyn technology, we look forward to advancing our U.S. clinical program and exploring additional commercial opportunities with our current and future partners."

Oculus presented positive results from the recently completed U.S. Phase II trial assessing

the safety and efficacy of the Microcyn Technology in the treatment of mildly infected diabetic foot ulcers at DFCon 08, a premier international diabetic foot conference held in March: [http://www.oculusis.com/phase2data\\_update/](http://www.oculusis.com/phase2data_update/).

## About Oculus

Oculus Innovative Sciences is a biopharmaceutical company that develops, manufactures and markets a family of products based upon the Microcyn(R) Technology platform, which is intended to help prevent and treat infections in chronic and acute wounds. The Microcyn Technology platform is a biocompatible, shelf-stable solution containing active oxychlorine compounds that is currently commercialized outside the United States for the treatment of infected wounds. The solutions derived from the Microcyn Technology platform have demonstrated, in a variety of research and investigational studies, the ability to treat a wide range of pathogens, including antibiotic-resistant strains of bacteria (including MRSA and VRE), viruses, fungi and spores.

The technology has also demonstrated wound healing in chronic and acute wounds in clinical investigational studies. A recently completed U.S. Phase II clinical trial of Microcyn Technology met the primary endpoints of safety and efficacy for the treatment of mildly infected diabetic foot ulcers.

Oculus' principal operations are in Petaluma, California, and it conducts operations in Europe, Latin America and Japan through its wholly owned subsidiaries, Oculus Innovative Sciences Netherlands B.V., Oculus Technologies of Mexico, S.A. de C.V. and Oculus Japan K.K. Oculus' website is [www.oculusis.com](http://www.oculusis.com).

## Forward-Looking Statements

Except for historical information herein, some 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 our belief that the design of our Phase II trial should provide important information for our planned Phase III trial or that our Phase II trials will be sufficient to allow the Company to move forward in its clinical program. These forward-looking statements are identified by the use of words such as "could," "suggest," "advancing," and "exploring," 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 risks inherent in the development and commercialization of potential products, the risk that regulatory clinical and guideline developments may change, the risk that scientific data may not be sufficient to meet regulatory standards or receipt of required regulatory clearances or approvals, the risk that clinical results may not be replicated in actual patient settings, the risk that protection offered by our patents and patent applications may be challenged, invalidated or circumvented by our competitors, the risk that present trends will continue and that the available market for our products will not be as large as expected, the risk that our products will not be able to penetrate one or more targeted markets, the risk that revenues will not be sufficient to fund further development and clinical studies, the Company's future capital needs, and its ability to obtain additional funding and other risks detailed from time to time in the Company's filings with the Securities and Exchange Commission including the quarterly report on Form 10-Q for the quarter ended December 31, 2007. Oculus Innovative Sciences disclaims any obligation to update these forward-looking statements.

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Source: Oculus Innovative Sciences, Inc.