

Oculus Innovative Sciences Announces Additional Phase II Data for Microcyn(R) Technology in Mildly Infected Diabetic Foot Ulcers

- -- Met Primary Endpoint of Clinical Cure or Improvement of Infection in Intent-to-Treat Patient Population
- -- 93% Clinical Success Rate in Clinically Evaluable (CE) Population Compared to 56% in Levofloxacin Plus Saline Arm at Day 24, Test of Cure Visit (p = 0.033)
- -- Per-Patient Microbiological Response Shows 95% Confidence Intervals Overlap in All Three Arms at Day 10, End of Therapy Visit
- -- Webcast/Teleconference Today at 9:30 a.m. (PDT) to Include Supporting Data from Two Recent International Studies Evaluating Microcyn Technology in the Treatment of Infected Diabetic Foot Ulcers

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

Oculus Innovative Sciences, Inc. (Nasdaq:OCLS) today announced additional positive results from its U.S. Phase II clinical trial evaluating Microcyn(R) Technology as a topical antimicrobial treatment for mildly infected diabetic foot ulcers. In the clinically evaluable population of the study (those that complied with the protocol requirements for the duration of the study), the clinical success rate at visit 3 (End of Therapy) for Microcyn-alone-treated patients was 77.8% compared to 61.1% for the levofloxacin plus saline treated patients. Interestingly, the clinical success rate at visit 4 (Test of Cure) for Microcyn-alone-treated patients increased to 93.3% compared to 56.3% for the levofloxacin plus saline-treated patients (p= 0.033). This study was not statistically powered but the high clinical success rate (93.3%) and the p-value (0.033) would suggest the difference is meaningfully positive for the Microcyn-treated patients.

Andres A. Gutierrez M.D., Ph.D., director of medical affairs, stated, "This is a remarkable result and certainly not one you would expect in a smaller study. We feel this result, along with previously reported clinical success data in our Phase II trial, supportive published results in the literature, and even data presented here at DFCon, all suggest that Microcyn Technology has a potential significant role in the treatment of infected diabetic foot ulcers."

No serious drug-related adverse events were reported in any of the three treatment arms. In the Microcyn-Levofloxacin combination arm, two patients experienced stomach discomfort and amnesia, respectively, both "probably related" to levofloxacin. One patient experienced a burning sensation that was "definitely related" to Microcyn, which is consistent with observations in prior Microcyn studies.

Additionally, in the original announced top-line results based upon a preliminary review of the raw data, it appears there were fewer eradications of bacterial strains in the Microcyn monotherapy arm than in the other two arms. The company continues to analyze the microbiological responses and has identified the overlap of confidence intervals of perpatient microbiological response in the three groups. This would suggest there is not a significant difference between the three treatment arms relative to the per-patient microbiological response.

The company plans to request an end-of-Phase II meeting with the FDA to discuss Phase II results and define the scope and parameters for advancing the clinical program to a New Drug Application.

Top-line results announced February 27, 2008:

Microcyn (Monotherapy) Saline + Levofloxacin Levofloxacin	Clinical Cu	re	or Impro	vement of	:	Infection	at Days	10) and 24	(ITT)	
Day 10 Clinical Success (Primary Endpoint)			-						-		
Clinical Success (Primary Endpoint) 15 75% 12 57% 16 64% Cure 6 30% 7 33% 9 36% Improvement 9 45% 5 24% 7 28% Day 24 Clinical Success (Follow-Up Visit) 15 75% 11 52% 18 72% Cure 11 55% 6 29% 11 44% Improvement 4 20% 5 24% 7 28% Intent to Treat (ITT) Population		#	Patients	Percent	#	Patients	Percent	#	Patients	Percent	
Success (Primary Endpoint) 15 75% 12 57% 16 64% Cure 6 30% 7 33% 9 36% Improvement 9 45% 5 24% 7 28% Day 24 Clinical Success (Follow-Up Visit) 15 75% 11 52% 18 72% Cure 11 55% 6 29% 11 44% Improvement 4 20% 5 24% 7 28% Intent to Treat (ITT) Population	Day 10				_						
Endpoint) 15 75% 12 57% 16 64% Cure 6 30% 7 33% 9 36% Improvement 9 45% 5 24% 7 28% Day 24 Clinical Success (Follow-Up Visit) 15 75% 11 52% 18 72% Cure 11 55% 6 29% 11 44% Improvement 4 20% 5 24% 7 28% Intent to Treat (ITT) Population	Success										
<pre>Improvement 9 45% 5 24% 7 28%</pre> Day 24 Clinical Success (Follow-Up Visit) 15 75% 11 52% 18 72%			15	75%		12	57%		16	64%	
Day 24 Clinical Success (Follow-Up Visit) 15 75% 11 52% 18 72% Cure 11 55% 6 29% 11 44% Improvement 4 20% 5 24% 7 28% Intent to Treat (ITT) Population	Cure		6	30%		7	33%		9	36%	
Clinical Success (Follow-Up Visit) 15 75% 11 52% 18 72% Cure 11 55% 6 29% 11 44% Improvement 4 20% 5 24% 7 28% Intent to Treat (ITT) Population	Improvement		9	45%		5	24%		7	28%	
Success (Follow-Up Visit) 15 75% 11 52% 18 72% Cure 11 55% 6 29% 11 44% Improvement 4 20% 5 24% 7 28% Intent to Treat (ITT) Population	Day 24										
Cure 11 55% 6 29% 11 44% Improvement 4 20% 5 24% 7 28% Intent to Treat (ITT) Population	Success (Follow-Up			5 50			500		1.0	500	
Improvement 4 20% 5 24% 7 28% Intent to Treat (ITT) Population											
Intent to Treat (ITT) Population											
Treat (ITT) Population							240				
(a) 20 21 25	Treat (ITT) Population										
	(a)		20 			21 			25 		

⁽a) Intent-to Treat (ITT) Sample: All randomized subjects having taken at least one dose of study drug and having provided any on-treatment data. Percentages are based on the number of ITT patients in each treatment group.

Newly released Clinically Evaluable (CE) population results:

Clinical Cure or Improvement of Infection at Days 10 and 24 (Clinically Evaluable Patients)

(Clinically Evaluable Patients)										
		Microcyn (Monotherapy)			Saline + Levofloxacin			Microcyn + Levofloxacin		
	#	Patients	Percent	#	Patients	Percent	#	Patients	Percent	
Day 10 Clinical Success (Primary Endpoint)		14	78%		11	61%		14	70%	
Cure Improvement		6 8	33% 44%		7 4	39% 22%		8 6 	40% 30%	
Day 24 Clinical Success (follow up visit)		14	93%		9	56%		15	83%	
Cure Improvement		10 4	67% 27%		5 4	31% 25%		10 5	56% 28%	
P-value for Comparison of Clinical Success Rate Microcyn monotherapy vs. levofloxacin + saline					0.033	3				
Clinically Evaluable Population Day 24		15			16			18		

Hoji Alimi, CEO and founder of Oculus Innovative Sciences, said, "This additional data reaffirms our belief that Microcyn has the potential to be a benefit to patients with infected diabetic foot ulcers. Microcyn demonstrated a positive clinical success rate, meeting the primary endpoint of clinical cure or improvement of infection. We continue to focus on further analysis of the complete trial data to prepare for our end-of-Phase II meeting with the FDA."

Conference Call Information

Oculus will host a webcast and teleconference at 9:30 a.m. PDT (12:30 p.m. EDT) today (Friday, March 14, 2008), to discuss additional data from the Phase II clinical trial of Microcyn Technology in patients with mildly infected diabetic foot ulcers. Supporting results from two international studies of Microcyn Technology, completed in Italy and India, will be

presented as well:

- -- Phase II data will be presented by the study's principal investigator, Adam Landsman, DPM and Ph.D., of Beth Israel Deaconess Medical Center in Boston.
- -- Dr. Alberto Piagessi of the Azienda Ospedaliera Universitaria in Pisana, Italy, will review his 39-patient prospective and randomized study, "Efficacy and Safety of a Novel, Super-Oxidized Solution in Managing Post-Surgical Lesions of the Diabetic Foot."
- -- Amar Pal Sing Suri, DPM, of the Diabetic Footcare Center in New Delhi, India will present a summary of his 100-patient randomized trial entitled, "The Effect of Neutral-pH Super-Oxidized Solution for the Treatment of Infected Diabetic Foot Wounds."

The live webcast over the Internet will be available at http://ir.oculusis.com/events.cfm and archived for 30 days. Please access the site 15 minutes before the presentation in the event that a software download is required. To listen over the phone, please call 1-877-407-4018 (domestic/toll-free) or 1-201-689-8471 (international). A telephone replay will be available for 30 days after the call at 1-877-660-6853 (domestic/toll-free), or 1-201-612-7415 (international). Please enter account number 3055 and conference identification number 278320.

About the Phase II Trial

The Phase II randomized, open-label study enrolled a total of 66 patients with mildly infected diabetic foot ulcers at 15 U.S. sites. Three treatment arms were evaluated: 1) 20 patients (15 evaluable) received topical Microcyn alone 2) 25 patients (18 evaluable) received topical Microcyn in combination with oral levofloxacin; and 3) 21 patients (16 evaluable) received topical saline in combination with oral levofloxacin.

Patient enrollment criteria in all three treatment arms of the study included appropriate blood perfusion and mildly infected ulcers defined by IDSA classification of "mild" and University of Texas wound classification of "1B." Patients were randomized and treated for a total of 10 days. Designed into the trial were three assessment time points: day three, day 10, and day 24. The design provided flexibility for an optimal design of a Phase III trial based on a number of potential positive signals at various time points.

The primary Phase II endpoint was clinical cure or improvement of infection at the end of therapy (day 10). Clinical cure of infection is defined as the elimination of all five of the Infectious Diseases Society of America (IDSA) visual symptoms that characterize mildly infected diabetic foot ulcers, including: 1) presence of erythema less than two centimeters around the ulcer, 2) detectable increase in temperature of the wound or periwound area, 3) culturable exudate and/or extension of redness is present, 4) localized swelling or induration, and 5) localized tenderness or pain. Clinical improvement of infection is defined as the elimination of at least two of the five ISDA symptomatic visual indications.

Levofloxacin was chosen for the control group because it is one of the more potent, broadspectrum oral antibiotics indicated for the treatment of complicated skin and skin structure infections (CSSSIs). IDSA guidelines also recognize Levofloxacin as an appropriate treatment for the treatment of diabetic foot infections. According to the Datamonitor Pharmaceutical Report, Levofloxacin generated \$2.4 billion in global sales in 2005.

Diabetes and Diabetic Foot Ulcers

According to the American Diabetes Association, 20.8 million children and adults in the United States, or 7% of the population, are afflicted with diabetes. If present trends continue, one in three Americans that were born in 2000 will develop diabetes during their lifetime. Each day, approximately 4,110 people are diagnosed with diabetes. The average cost of treatment is \$8,000 for a single ulcer, \$17,000 for an infected ulcer, and \$45,000 for an ulcer requiring major amputation. More than 80,000 amputations are performed each year on diabetic patients in the United States. 50% of patients who have undergone amputations will develop ulcerations and infections in the contralateral limb within 18 months, while 58% will have a contralateral amputation three to five years after the first amputation. In addition, the estimated three-year mortality rate is as high as 20%-50% after a first amputation. These figures have not changed much in the past 30 years, despite huge advances in the medical and surgical treatment of patients with diabetes.

A 2006 study published in Clinical Diabetes by Ingrid Kruse, DPM, and Steven Edelman, M.D., indicated that diabetic foot problems, such as ulcerations, infections, and gangrene, are the most common causes of hospitalization among diabetic patients. Routine ulcer care, treatment of infections, amputations, and hospitalizations cost billions of dollars every year and place a tremendous burden on the health care system.

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 solution containing active oxychlorine compounds. 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. It has been commercialized outside of the United States for the treatment of infected wounds.

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.

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 plans to request a meeting with the FDA, our belief that the design of our Phase II trial should provide important information for our planned Phase III trial, our ability to provide expanded analysis, 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 "suggest," "potential," "believe," "expect," "plans," "advancing," and "should," 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 forwardlooking statements.

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Source: Oculus Innovative Sciences, Inc.