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Oculus Innovative Sciences Holds Successful End-of-Phase II Meeting with FDA for Microcyn(R) Technology

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

Oculus Innovative Sciences, Inc. (Nasdaq:OCLS) today announced that the company held a successful End-of-Phase II meeting with the U.S. Food and Drug Administration (FDA) on August 29, 2008. Following a review of the Phase II data on Microcyn(R) Technology for the treatment of mildly infected diabetic foot ulcers, the FDA agreed:

- Oculus may move forward into the pivotal phase of its U.S. clinical program for Microcyn Technology.

- There were no safety issues relative to moving into this next clinical phase immediately, and carcinogenicity studies will not be required for product approval.

- Clinical requirements for efficacy and safety for a new drug application (NDA) will be appropriately accounted for within the agreed upon pivotal trial designs.

"While we will continue to dialogue with the FDA on the specifics of the pivotal trial designs, the agreements from this meeting permit us to move forward in our efforts to secure a pharmaceutical partner for this next phase of our U.S. clinical studies," said Hoji Alimi, CEO and founder of Oculus. "We have made the strategic decision to pursue ongoing development of the Microcyn Technology as a drug in the United States with a corporate partner. We believe this is the best approach for our shareholders and for the development of our Microcyn Technology, which has the potential to become the first FDA-approved topical anti-infective for the treatment of diabetic foot ulcer infections."

In December 2007, the company completed its Phase II clinical trial evaluating Microcyn Technology as a topical antimicrobial treatment for mildly infected diabetic foot ulcers. In March of this year, the company announced positive results with a clinical success rate in the clinically evaluable population at visit 4 (Test of Cure) of 93.3% for patients treated with Microcyn alone, compared with 56.3% for patients treated with levofloxacin plus saline.

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 Infectious Diseases Society of America (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 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 IDSA symptomatic visual indications.

Levofloxacin was chosen for the control group because it is one of the more potent, broad-spectrum oral antibiotics indicated for the treatment of complicated skin and skin structure infections. IDSA guidelines also recognize levofloxacin as an appropriate oral antimicrobial 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 Americans, or seven percent of the population, are afflicted with diabetes. If present trends continue, one in three Americans 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 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 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 features a biocompatible, shelf-stable solution containing active oxychlorine compounds that is

currently commercialized primarily in Europe, India, China and Mexico for the treatment of infected wounds. The solutions derived from this 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.

Oculus also develops, manufactures and markets a number of devices and products under 510(k) regulatory approvals to professionals and consumers. The company's headquarters are in Petaluma, California, with operations in Europe, Latin America and Japan. More information can be found at 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 Microcyn's safety, efficacy and wound healing capabilities, the ability of Microcyn to become a new type of drug for comprehensive treatment of infected diabetic foot ulcers and our ability to identify or align ourselves with new partners. These forward-looking statements are identified by the use of words such as "may," "continue," "move," and "secure," 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 treatment 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 our work force is inadequate to implement our business plan, the risk that we are unable to identify or align ourselves with strategic partners, 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 annual report on Form 10-K for the year ended March 31, 2008. Oculus Innovative Sciences disclaims any obligation to update these forward-looking statements.

Source: Oculus Innovative Sciences, Inc.