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Oculus Innovative Sciences Completes Enrollment of Phase II Trial of Microcyn(R) Technology in Treatment of Mildly Infected Diabetic Foot Ulcers

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

Oculus Innovative Sciences, Inc. (NASDAQ:OCLS) today announced completion of enrollment of its Phase II clinical trial of Microcyn(R) Technology. The company has enrolled and randomized 67 patients in its open-label Phase II clinical trial evaluating its Microcyn Technology in the treatment of mildly infected diabetic foot ulcers. The study, which is being conducted at 15 U.S. sites, is specifically designed to demonstrate that topical Microcyn has sufficiently similar cure and improvement rates to oral levofloxacin. This would provide the rationale for larger Phase III trials designed to demonstrate statistically significant safety and efficacy, fundamental in securing NDA marketing approval. Also being examined are a number of other trial parameters for consideration in the design of the larger Phase III trials that will be required for FDA approval. The company expects to provide preliminary top line results in the first calendar quarter of 2008.

"Completing enrollment for the Phase II trial is a major milestone for Oculus and our Microcyn Technology," stated Hoji Alimi, chairman and CEO of Oculus Innovative Sciences. "It underscores the success of our strategic direction, which is to invest in our U.S. clinical trial program for Microcyn. We believe this strategy will provide the greatest long-term return to Oculus' investors. We look forward to reporting preliminary top line data from the trial in the first calendar quarter of 2008."

The trial is evaluating three different treatment arms: 1) topical Microcyn alone 2) topical Microcyn in combination with oral levofloxacin; and 3) oral levofloxacin plus topical saline. Each patient will receive 10 days of treatment with a 14-day follow-up. Designed into the trial are three assessment time points: day 3, day 10, and day 24. This design allows for various options to analyze the data which will provide important information for the design of the Phase III trial.

"We have been diligently preparing for an end-of-Phase II meeting with the FDA," said Dr. Andres Gutierrez, director of medical affairs for Oculus. "We remain optimistic that our clinical program will continue to move ahead. We are looking forward to reviewing the data that we plan to announce in Q1 2008. We intend to submit the results for presentation at a major medical conference and will pursue publication of the results as soon as practical."

Further information on this Phase II trial can be found at www.clinicaltrials.gov.

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 U.S. 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 ability to replicate the results of the test in clinical trials, if at all, or for such trials or other tests to establish the conclusions suggested by the results of the test. These forward-looking statements are identified by the use of words such as "believe" "reporting," "remain," "expects," "designed," "will provide," "will pursue," "intend", and "examined," among others. These forward-looking statements are based on Oculus Innovative Sciences, Inc.'s current expectations. Investors are cautioned that such forward-looking statements in this press release are subject to certain risks and uncertainties inherent in the Company's business including risks inherent in the development and commercialization of potential products, the risk that scientific data may not be sufficient to meet regulatory standards or receipt of required regulatory clearances or approvals, risks that revenues will not reach expected levels, 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 September 30, 2007 and Form 10-K for the fiscal year ended March 31, 2007. Oculus Innovative Sciences disclaims any obligation to update these forward-looking statements.

Source: Oculus Innovative Sciences, Inc.