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Oculus Initiates Patient Enrollment in Phase II Study of Microcyn(R) Technology for Treatment of Mild Diabetic Foot Infections

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

Oculus Innovative Sciences, Inc. (NASDAQ:OCLS) announced today that it has enrolled the first patient in a 60-patient, randomized and open-label Phase II trial to evaluate the preliminary safety and efficacy of topical Dermacyn(R) Wound Care versus systemic oral antibiotics for the treatment of mild diabetic foot infections. Dermacyn is a non-irritating proprietary oxychlorine formulation manufactured using Oculus' Microcyn(R) Technology. The primary efficacy endpoint of the trial will be clinical cure or improvement of infection. Oculus expects results from the study in the third quarter of 2007, followed by the initiation of two larger, pivotal Phase III trials.

Hoji Alimi, president and CEO of Oculus, commented, "Our primary focus is on the initiation and successful completion of the Phase II trial which is an important milestone for Oculus as we pursue our strategic goal to receive FDA approval of Dermacyn as a drug for the treatment of infection in the United States. Positive results from 12 international studies provided the proof of concept for proceeding to this Phase II trial in the U.S." An additional eight studies have confirmed the technology's safety and effectiveness.

About the Study

The randomized, open-label three-arm study will enroll 60 total patients at up to 15 U.S. sites. Patients will be randomized 3:1 to receive Dermacyn, Dermacyn in combination with the oral antibiotic levofloxacin, or saline plus levofloxacin. The twenty patients in each arm will be treated over ten days, each time their wound dressing is reapplied. After ten days, patients will stop treatment and return two weeks later for a follow-up assessment.

This is not a superiority or dose effectiveness study. The primary reason for conducting this Phase II study is to show Microcyn Technology has anti-infective properties in open wounds as has been shown in 20 clinical investigative studies. The protocol for this study has been reviewed by two separate medical advisory boards as well as the FDA. The ten study sites initiated to date are the North American Center for Limb Preservation in New Haven, Connecticut; Harrisburgh Foot and Ankle Center in Harrisburgh, Pennsylvania; Wasatch Clinical Research in Salt Lake City; Clinical Research of Tampa Bay in Florida; Northern California Foot and Ankle Center in Santa Rosa; Beth Israel Deaconess Medical Center/Harvard Medical School in Boston; SharpCare LLC in Louisville, Kentucky; Derm DX Center for Dermatology in Hazleton, Pennsylvania; The Whittier Institute for Diabetes in La

Jolla, California; and Wound Treatment & Research Center, UCSD in San Diego.

About Diabetic Foot Ulcers

The Centers for Disease Control and Prevention (CDC) estimates that the there are over 1.5 million new cases of diabetes diagnosed annually, and that overall the disease affects approximately seven percent of the U.S. population, or 20.8 million people. Foot ulcers are a common complication of diabetes, accounting for high morbidity and mortality, with an estimated 15% of diabetic patients expected to develop a lower extremity ulcer during the course of their disease. Infection in the presence of this peripheral vascular disease is the most important prognostic factor for the risk of amputation in the diabetic foot. It has been estimated that an amputation related to diabetes occurs somewhere in the world every 30 seconds.

About Oculus

Oculus Innovative Sciences is a biopharmaceutical company that develops, manufactures and markets a family of Microcyn(R) Technology-based products intended to help prevent and treat infections in chronic and acute wounds. Oculus' platform technology, called Microcyn, is a non-irritating proprietary oxychlorine formulation designed to treat a wide range of pathogens, including antibiotic-resistant strains of bacteria, viruses, fungi and spores.

Oculus' principal operations are in Petaluma, California, and it conducts operations in Europe and Latin America through its wholly-owned subsidiaries, Oculus Innovative Sciences Netherlands B.V. and Oculus Technologies of Mexico, S.A. de C.V. Our website is www.oculusis.com.

Forward-Looking Statements

Except for historical information herein, the 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. These forward-looking statements are identified by the use of words such as "will be," "intends," "will enroll," and "initiation," among others. These forward-looking statements are subject to certain risks and uncertainties that could cause actual results to differ materially, including risks inherent in the development and commercialization of potential products, the risk that clinical studies or trials will not proceed as anticipated or may not be successful or sufficient to meet regulatory standards or receipt of required regulatory clearances or approvals, 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, 2006. Oculus Innovative Sciences disclaims any obligation to update these forward-looking statements.

Source: Oculus Innovative Sciences, Inc.