

## Oculus Treatment Effective Against Diabetic Foot Infections

By Luke Timmerman  
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**Feb. 27 (Bloomberg)** -- Oculus Innovative Sciences Inc., developer of the chlorine-based skin infection treatment Microcyn, said the drug was effective in treating diabetic foot ulcers, the leading cause of leg amputation in the U.S.

Oculus's therapy eliminated or reduced infection for three-fourths of patients after 10 days, compared with 57 percent who did that well on a standard saline rinse and levofloxacin, an antibiotic, the company said today in a statement. The benefit was sustained for at least 24 days for all patients on the Oculus drug, and all but one patient in the control group.

The results from the 66-patient study mark the first time the Microcyn technology has been tested directly against a standard treatment for infections. If the advantage can be confirmed in larger trials, it could offer a way to avoid overuse of antibiotics and provide a new option for treating diabetic foot ulcers, which lead to 80,000 amputations in the U.S. each year, Oculus said.

"This data will take the market by surprise," said Hoji Alimi, Oculus' chief executive officer, in a telephone interview. "Levofloxacin is an extremely potent antibiotic, and to go against it and come away with these kind of numbers will be viewed positively."

Oculus rose 52 cents, or 9.1 percent, to \$6.25 in Nasdaq Stock Market composite trading at 9:59 a.m. New York time. That compares with a record \$11 on July 18, and \$8 on the first day of public trading on Jan. 24, 2007. Oculus is based in Petaluma, California.

### Chlorine Compounds

Oculus's Microcyn is a proprietary formulation of oxygen and chlorine compounds that is designed to kill multiple types of germs, such as viruses, fungi and bacteria, including MRSA, or antibiotic-resistant bacteria. It is delivered as a liquid rinse on a chronic skin wound, and soaked in bandages, Alimi said.

The new approach may have an advantage over existing treatments, because it is localized, and doesn't need to circulate through the bloodstream like antibiotics, Alimi said. Diabetic patients often have poor circulation in their legs, making it difficult for antibiotics to be effective, he said.

Patients enrolled in the trial took the Microcyn compounds or the standard saline in combination with the antibiotic levofloxacin, marketed as Johnson & Johnson's Levaquin. A third group took the Oculus product in combination with the antibiotic.

No serious side effects were reported among patients in the trial, Oculus said. One patient experienced a burning sensation from the Microcyn, consistent with previous studies, the company said.

### **FDA Discussion**

The company plans to discuss the findings with the U.S. Food and Drug Administration, along with future development plans, said Michael Wokasch, the company's chief operating officer. It's likely the company will need to run two clinical trials of more than 300 patients each to demonstrate a statistically significant benefit for its product to win FDA approval. It could take two years to conduct the trials, Alimi said.

Oculus markets the product in the European Union, Mexico and India, Alimi said. If successful in the U.S., it hopes to broaden use to other chronic skin infections, such as bed sores, he said.

The company was founded in 1999, and had an accumulated deficit of \$86 million at the end of 2007, the company said in its most recent quarterly report with the Securities and Exchange Commission.

Oculus had \$10.4 million in cash at the end of 2007, and will need to raise "a significant amount of capital" to pay for trials needed to win FDA approval, the company said in the filing.

--Editors: Angela Zimm, Andrew Pollack