



Visiogen, Inc. Receives FDA Approval to Expand its U.S. Clinical Trial
Expansion of Trial Will Allow Researchers to Further Validate Safety and Effectiveness of the Investigational Synchrony® Dual Optic Accommodating Intraocular Lens

IRVINE, CA., January 17, 2007—Visiogen, Inc. of Irvine, California, announced it has received approval from the U.S. Food & Drug Administration (FDA) for full expansion of its Phase III U.S. clinical trial for its Synchrony® dual optic accommodating intraocular lens. Already approved for use throughout the European Union, the Synchrony system is being studied in a multi-center trial in the U.S. to evaluate safety and effectiveness and the potential for near and intermediate vision without the use of spectacles in patients post cataract surgery.

“Full expansion of the clinical trial for Synchrony is another significant step toward our ultimate goal of approval for use within the United States,” according to Barbara Niksch, Vice President of Regulatory, Quality & Clinical Affairs at Visiogen.

The proprietary Synchrony system, intended for use in cataract and refractive patients, incorporates a dual optic lens with an easy-to-use pre-loaded injector. The entire system is self-contained and ready for use without the need for lens handling. The dual optic lens can be inserted through a 3.6 – 3.8 mm clear-corneal incision. The single-piece silicone lens unfolds in the eye upon insertion and features two optics connected by a spring system. The springs connect a 5.5-mm high power anterior optic and a 6-mm negative power posterior optic; the spring action moves the front optic and changes the eye’s focus from near to far. This unique combination of positive- and negative-powered optics is customized for each patient.

To date, the Synchrony lens has been implanted in over 400 patients worldwide. The company announced that it had received the European CE Mark for the Synchrony® Dual Optic

Accommodating IOL in June of 2006, which allows them to expand into post-marketing research studies within Europe to further build the scientific foundation for Synchrony.

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About Visiogen

Visiogen, Inc. is focused on developing innovative products for cataract and refractive patients. Founded in Irvine, California, in 2001, Visiogen's first commercial application, Synchrony®, a dual optic accommodating intraocular lens and pre-loaded injector, is currently in clinical studies in the U.S. and recently received the CE Mark in Europe.

More information on the company and its offerings can be obtained by contacting:

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