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Clearside Biomedical Announces First Successful Human Dosing In a Safety and Tolerability Study in Patients with Retinal Disease

Initial safety data show that the microinjection technique appears to be safe and well-tolerated

ATLANTA, GA. (November 6, 2012) — Clearside Biomedical, Inc., a privately held company specializing in the research and development of ophthalmic pharmaceuticals, today announced the successful dosing of patients in a safety and tolerability clinical study using its proprietary ocular microinjection platform to deliver therapeutics to treat retinal disease.

"I am extremely proud of the Clearside Biomedical research and development group for reaching our milestone of conducting a clinical trial within less than a year of receiving funding," said Daniel White, President and CEO of Clearside Biomedical. "The treatment of these patients is an important step in the development of the microinjection platform as a preferred technique for delivering drugs to the retina and choroid through the suprachoroidal space within the current standards of medical practice in vitreo-retinal medicine."

The open-label safety and tolerability study involved the administration of bevacizumab into the suprachoroidal space (SCS) of the eye using Clearside Biomedical's proprietary microinjection platform. The clinical trial was conducted by Principal Investigator Dr. Virgilio Morales-Cantón, who is the head of the Retina and Vitreous Department at the Asociación para Evitar la Ceguera (APEC) in Mexico City. Administration to the SCS was achieved in all patients and was confirmed via ophthalmoscope. The four patients in the trial suffer from advanced, wet age-related macular degeneration (AMD). AMD is a deterioration of the eye's macula, a small area in the retina that is responsible for central vision. AMD can eventually lead to blindness if left untreated.

"In my opinion, this study is pivotal for the company since it demonstrated that the suprachoroidal microinjection procedure was well tolerated by the patient," said Dr. Peter K. Kaiser, Professor of Ophthalmology and retina specialist at the Cole Eye Institute at the Cleveland Clinic. "It was done only with topical anesthesia, making this a viable procedure to deliver medications to the retina and choroid."

Clearside Biomedical's in-office injection procedure delivers drugs choroid and retina through the suprachoroidal space, a tissue compartment within the eye, allowing medication to be applied directly to the area affected by disease. As demonstrated in previous nonclinical studies and the initial clinical study, dosing into the SCS appears to be safe and well-tolerated in the first month of safety assessments.

Company plans to File and IND on CLS 1001:

Clearside Biomedical held a pre-IND meeting with the U.S. Food and Drug Administration to discuss the development plan of its initial product, CLS 1001. Based on this meeting, the company plans to file an Investigational New Drug (IND) application by the end of the year to enable initiation of the clinical program in the United States.

The original technology was developed collaboratively by the Emory University School of Medicine and Georgia Institute of Technology, and Clearside Biomedical received an initial $4 million in funding in January 2012 from Hatteras Venture Partners, Georgia Research Alliance Venture Fund and Kenan Flagler Venture Fund. Based on the straightforward regulatory path for the initial product, CLS 1001, Clearside Biomedical anticipates raising additional capital through a series B round to initiate and complete pivotal testing of the product candidate and to file a new drug application.

About Clearside Biomedical

Clearside Biomedical is an Atlanta-based, clinical phase ophthalmic pharmaceutical company improving drug performance through tissue-targeted microinjection into distinct compartments of the eye to treat sight-threatening disease. Clearside Biomedical's proprietary microinjection dosing platform consistently delivers drug to the suprachoroidal space (SCS) and will allow professionals to treat patients in their offices without complicated surgical techniques or delivery modalities. Local administration of pharmaceuticals to the suprachoroidal space is ideal for treating posterior inflammation and choroidal neovascularization, which are important pathologies to target in the treatment of retinal blindness. Clearside Biomedical was founded by an executive team with extensive development and revenue growth expertise, focused on improving the delivery of therapeutic agents to improve standard of care for patients with sight-threatening disease. Visit www.clearsidebio.com for more information.

Contact:

Charles Deignan, 678.270.4005