Clearside Biomedical, Inc. Completes Enrollment in Phase 2 Clinical Trial of CLS-TA for the Treatment of Retinal Vein Occlusion Using Suprachoroidal Space (SCS™) Drug Administration

December 14, 2015 1:43 AM ET

Alpharetta, GA (December 14, 2015) - Clearside Biomedical, Inc., a late-stage clinical biopharmaceutical company developing innovative first-in-class drug therapies to treat blinding diseases of the eye, today announced completion of enrollment in the company's Phase 2 clinical trial (Tanzanite) for the treatment of macular edema associated with retinal vein occlusion (RVO). The trial uses CLS-TA, Clearside's proprietary form of triamcinolone acetonide, injected by suprachoroidal space (SCS™) drug administration, concomitantly with aflibercept (Eylea®, Regeneron Pharmaceuticals) delivered intravitreally. Clearside expects to report top-line data from this clinical trial in the first half of 2016.

"I am extremely pleased with the commitment of the participating physicians and with our team who have contributed to our completing enrollment of patients in the Tanzanite trial," said Daniel H. White, CEO and President of Clearside. "We believe SCS™ drug administration of CLS-TA, in combination with a VEGF inhibitor, could reduce the frequency of required RVO treatments from monthly to quarterly."

The primary objective of the Tanzanite trial is to evaluate the safety and efficacy of a single SCS™ injection of CLS-TA together with an initial intravitreal injection of aflibercept, compared to the control group receiving only an intravitreal aflibercept injection. The primary efficacy endpoints in the trial include the number of patients in each arm eligible for additional aflibercept treatments, which we believe will provide an indication of whether concomitant therapy reduces the number of required aflibercept treatments. Secondary endpoints of the trial include change in visual acuity and reductions in retinal thickness from baseline. Safety endpoints are the incidence of treatment-emergent adverse events and serious adverse events, including increases in intraocular pressure (IOP).

Drug administration through the SCS™ potentially provides a route of access from the anterior region of the eye to treat diseases of the back-of-the-eye like RVO, uveitis, wet age-related macular edema (AMD) and diabetic macular edema (DME).

About Retinal Vein Occlusion

Retinal vein occlusion (RVO) is a sight-threatening disorder resulting from the blockage of one of the veins carrying blood out of the retina. RVO is estimated to affect more than 16 million adults worldwide, according to a 2010 study published in the journal *Ophthalmology*, and it is estimated that RVO affects 2.2 million adults in the United States. In RVO, the blockage of a retinal vein can lead to poor blood circulation, low oxygen and sometimes inflammation. A blocked vein will leak its contents of blood and fluid. Bleeding within the retina and swelling from the fluid can create macular edema.

About Clearside Biomedical, Inc.

Clearside Biomedical, Inc., headquartered in Alpharetta, GA, is a late-stage clinical biopharmaceutical company developing innovative first-in-class drug therapies to treat blinding diseases of the eye using Clearside's proprietary microinjector to reach diseased tissue through the SCS™. Clearside holds intellectual property protecting the delivery of drugs of any type through the SCS™ to reach the back of the eye. Visit www.clearsidebio.com for more information.

Contacts

Clearside Biomedical, Inc.

Company:

Charles Deignan
Chief Financial Officer
678-270-4005
charlie.deignan@clearsidebio.com

Investors:

Matthew Beck
The Trout Group
646-378-2933
mbeck@troutgroup.com