



Okogen Initiates Phase 2 Clinical Trial (RUBY) of OKG-0301 in Patients with Acute Adenoviral Conjunctivitis

- *219-patient study to be conducted at multiple clinical sites in Australia*

San Diego, CA and Melbourne, AUS – January 31, 2019 – Okogen, a clinical-stage, specialty biotechnology company focused on developing ophthalmic therapeutics, today announced the initiation of a Phase 2 clinical trial (RUBY) that is designed to evaluate the safety and efficacy of OKG-0301 in the treatment of acute adenoviral conjunctivitis. OKG-0301 is a topical ophthalmic formulation of ranpirnase, a targeted ribonuclease (RNase) with established broad-spectrum antiviral properties. RNases, naturally present in tears, have evolved as host defense tools and OKG-0301 functions through multiple mechanisms to halt viral replication and reduce inflammation.

Adenoviral conjunctivitis, a highly contagious disease, is the number one cause of eye infections globally. There are approximately 16 million cases of acute adenoviral conjunctivitis annually worldwide, with 4 million cases in the United States alone. Approximately 70% of U.S. adenoviral conjunctivitis patients seek treatment each year, constituting about 1% of all primary care visits annually. Infected patients suffer eye redness with swelling and ocular discharge, accompanied by symptoms including pain, itching, and foreign body sensation. The infection typically lasts for 2-3 weeks, with patients remaining contagious for 10-14 days after first onset of disease. Transmission to a patient's other eye, family members or close contacts is extremely common; patients are advised to avoid work and/or school until symptoms fully resolve. There are no approved treatments for adenoviral conjunctivitis.

“We are very excited to test OKG-0301's ability to positively impact patients with adenoviral conjunctivitis, a potentially serious infectious disease for which there currently are no therapies that address the underlying infection,” said Brian M. Strem, Chief Executive Officer at Okogen. “Reducing the highly contagious nature of this infection while accelerating the resolution of symptoms has been a long-sought goal of the ophthalmology community. The existing body of OKG-0301 data suggests that this innovative antiviral agent can achieve both of these clinically important outcomes. We are excited to initiate this Phase 2 trial and expect to complete enrollment by the end of 2019.”

The RUBY trial is a phase 2, multicenter, randomized, placebo-controlled, double-masked clinical trial evaluating multiple doses of OKG-0301 in 219 adult patients with acute adenoviral conjunctivitis. The coordinating principle investigator is Professor Stephanie Watson, Save Sight Institute, University of Sydney. Six to seven additional sites in Australia will participate in the trial. The study will evaluate the ability of OKG-0301 to reduce viral burden, which is critical to limiting the extent of disease as well as stopping the aggressive spread of virus. In addition, investigators will assess OKG-0301's safety and its potential to diminish longer-term complications of adenoviral infection that negatively affect vision and lead to scarring of the ocular surface.

Professor Watson commented: “I have been impressed with the consistent results of OKG-0301 in laboratory models of adenoviral conjunctivitis. My fellow investigators and I are excited to have the opportunity to evaluate how this novel antiviral therapy may be able to help patients suffering from this very common condition.”

About Okogen

Okogen is a clinical-stage, specialty biotechnology company focused on developing therapeutics to help patients with ocular diseases. The company’s lead development candidate, OKG-0301, is a broad-spectrum antiviral that functions intracellularly to inhibit viral replication and reduce inflammation. These mechanisms of action are expected to provide clinical benefit in addressing adenoviral infections of the eye as well as other classes of viruses that are active in the ocular space, including herpes simplex virus, varicella-zoster virus, picornavirus, and more.

For more information about Okogen, visit www.okogen.com. To learn more about the RUBY trial, visit www.rubytrial.com.au.

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