



FOR IMMEDIATE RELEASE

AVELLINO LABS RECEIVES CLIA CERTIFICATION FOR ITS AVAGEN GENETIC DIAGNOSTIC TEST FOR KERATOCONUS AND CORNEAL DYSTROPHIES

Genetic Diagnostic and Therapeutic Technology Company Initiates a Controlled Market Introduction of AveGen in the U.S. with Nationwide Roll-out Expected in 2020

Menlo Park, Calif. Oct. 14, 2019 -- Avellino Labs, global biotechnology and genetic science innovators, announced today the company received Clinical Laboratory Improvement Amendments (CLIA) for its AvaGen product, the first genetic test for determining risk of keratoconus and the presence of corneal dystrophies.

With CLIA certification of the Avellino Labs Menlo Park facility, effective immediately, the company now is able to receive and analyze patient samples with the novel AvaGen diagnostic tool for the identification of genetic risk factors associated with keratoconus and a variety of corneal dystrophies.

“Our CLIA certification recognizes our commitment to the strictest quality criteria in clinical diagnostics, research and development, and data management to ensure our customers, and their patients, can leverage precision medicine with full confidence,” said James (Jim) V. Mazzo, Board member for Avellino Labs and Global President of Ophthalmic Devices at Carl Zeiss Meditec. “With AvaGen, physicians now have access to a new tool to provide a more precise medical consultation to their patients with the goal of providing a lifetime of healthy eye and vision care.”

This quarter, the company begins rolling out the availability of AvaGen in a controlled launch leading to nationwide availability of the genetic diagnostic in 2020.

AvaGen is the first commercially available genetic diagnostic test of its kind for keratoconus and corneal dystrophies. Utilizing state-of-science next generation sequencing (NGS) technology, AvaGen examines over 1,000 variants across 75 genes for keratoconus and over 70 mutations of the TGFBI gene for corneal dystrophies. With a simple in-office cheek swab, eye doctors can access actionable diagnostic data, forming the basis for preventative and mitigative strategies for patients.

"Simply put, AvaGen has the potential to save patients from future vision loss, especially at-risk patients, such as those with a family history of genetic eye disease," said Vance Thompson, M.D., director of refractive surgery, Vance Thompson Vision, and professor of ophthalmology at Sanford University of South Dakota School of Medicine. "Genetic testing like AvaGen offers a significant path forward to providing the personalized medicine I want to offer in my practice."

About Avellino Labs

Avellino Labs is a global leader in gene therapy and molecular diagnostics and the pioneer in precision medicine for eye care. Avellino Labs is pioneering CRISPR gene editing to manage and potentially cure inherited diseases. Avellino Labs continues to expand its diagnostics capabilities, leveraging genetic big data and algorithms to build on the success of the world's first DNA test to confirm the presence of genetic indicators that are positively associated with corneal dystrophies, providing life-changing information for patient treatment decisions and follow-up care. Avellino Labs is headquartered in Silicon Valley, California, with operations in Korea, Japan, China and the UK.

Avellino Labs was named a 2015 Technology Pioneer by the World Economic Forum based on its potential to impact global health.

To learn more, please visit <http://www.avellino.com/us/> or follow us on Twitter @Avellinolab_USA.

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