MEDIA RELEASE

For Immediate Release

AVELLINO LAUNCHES AVAGEN™ NATIONWIDE AS FIRST GENETIC TEST TO QUANTIFY KERATOCONUS RISK AND PRESENCE OF CORNEAL DYSTROPHIES

Novel Test Provides Early Understanding of Eye Disease to Enable Timely Treatment and More Informed Patient Management

MENLO PARK, Calif. – (June 2, 2021) – Avellino Lab USA, Inc. (Avellino) today announced full nationwide availability in the U.S. of AvaGen™, The Genetic Eye Test, as the first genetic test that helps determine a patient's risk of keratoconus and the presence of other corneal dystrophies. The test allows for more confident management and treatment for patients with these conditions in order to protect and preserve patient vision.

The test is designed to provide keratoconus patients with an earlier benefit from FDA-approved cross-linking treatment, which can halt disease progression and preserve vision. The AvaGen™ results can also influence an eye care professional's choice of refractive surgery options for patients.

The AvaGen™ genetic test examines 75 keratoconus-related genes and more than 2,000 variants of those genes to develop an actionable keratoconus genetic risk score. As certain ethnicities have a higher prevalence of this eye condition,[1] the AvaGen™ test also factors this information into its results. For corneal dystrophies, AvaGen™ determines the presence of any of the 70 TGFBI gene variants and provides a conclusive diagnosis of corneal dystrophy sub-types, such as Epithelial Basement Membrane, Granular and Lattice disease distinctions, Reis-Bucklers, Schnyder and Theill-Behnke.

"Assessing keratoconus is multi-factorial. Until now, genetic data has been missing from the equation. I order AvaGen™ when I have any red flag concerns in my refractive surgical evaluations, such as high astigmatism or steep corneal curvature, against-the-rule or irregular astigmatism in younger patients, a thin cornea, or in family members of a known keratoconus patient. AvaGen™ helps me know earlier about a patient's genetic predisposition and allows me to make confident treatment and management decisions," says Elizabeth Yeu, MD, of Virginia Eye Consultants, an advisor to Avellino.

Keratoconus is a progressive vision disorder affecting approximately 885,000 Americans[2] (1 in 375) that is often underdiagnosed or misdiagnosed in its earlier stages, when it can be better managed and treated to protect and preserve vision. Today's corneal diagnostic imaging tools often do not diagnose the disease early or misdiagnose keratoconus as astigmatism or myopia, and most optometrists do not have access to these imaging tools. Because of this, patients are typically managed with a "wait-and-see approach," which often results in a diagnosis only after vision has been impacted.

Corneal dystrophies are a rarer group of genetic diseases, which can cause not only vision loss but also pain and discomfort for the nearly 280,000 patients in the US[3] with some type of corneal dystrophy. Other diagnostic tools are often unable to provide a definitive diagnosis of the disease.

Avellino Chief Scientific Officer Nazneen Aziz, Ph.D., states, "We are pleased to make an impact on patients' lives by uncovering the genetic risk of sight-threatening diseases and enabling doctors to deliver a higher level of personalized, targeted eye care. AvaGen™ empowers eye care professionals with genetic data for everyday use in their medical practice so they can detect earlier the risk of developing keratoconus versus other, more traditional methods and take actionable decisions on the best course of treatment to protect and preserve vision."

Avellino CEO and President Jim Mazzo notes, "It is exciting to be part of transforming eye care with the national introduction of the first comprehensive genetic test for patients with these challenging conditions. I congratulate our Avellino team on accomplishing this important commercial milestone for the company, and for taking a giant step on our path to developing a host of genomic tests for personalized disease management."

He continues, "While we made AvaGen™ available in late 2019, we quickly pivoted our resources to do our part to address the COVID-19 pandemic over the last year with the development of our widely-used SARS-CoV-2/COVID-19 test, which received Emergency Use Authorization (EUA) from the FDA. Thanks to widespread testing and adoption of the COVID-19 vaccines, we are now able to offer AvaGen™ nationally."

AvaGen™ is designed to be easy to use, requiring only a simple cheek swab that is sent to Avellino's high complexity CLIA-certified lab for analysis. An eye care professional receives results in days in an intuitive and actionable report via a HIPAA-secured patient portal. Genetic counsel is provided alongside test results to ensure eye care professionals and their patients clearly understand the results and their implications for patient management.

About Avellino

Avellino Lab USA, Inc. is a global leader in gene therapy and molecular diagnostics at the forefront of precision medicine for eye care. With a long-term mission to develop personalized approaches to improve health and disease management through genomics, the company is developing a transformative genetic diagnostics product pipeline, as well as genetic therapeutics leveraging CRISPR gene editing, to better manage, and potentially cure, inherited diseases. The company also developed the Avellino SARS-CoV-2 RT-PCR diagnostic test to aid in COVID-19 pandemic testing efforts in the US, and was the third private company in the US to receive EUA for its COVID-19 test. Avellino is headquartered in Silicon Valley, California, with operations in Korea, Japan, China and the UK.

To learn more about Avellino, visit www.avellino.com.

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