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RetinalGenix Technologies Breakthrough in Real-Time 24/7 Remote Ocular Monitoring

High-Resolution Retinal Imaging Now Using Both Near Infrared And Green Modes

APOLLO BEACH, Fla., Feb. 20, 2025 (GLOBE NEWSWIRE) -- RetinalGenix Technologies Inc OTCQB:RTGN ("RetinalGenix" or the "Company"), announced today that it has achieved an important milestone in developing its high-resolution retinal imaging device and remote monitoring system. The Company has successfully started imaging patients with its first prototype of its device using both near-infrared and green modes. The images will be further enhanced for inclusion in the second prototype, and the design for manufacturing will now commence.

The imaging system is designed to enable secure, real-time remote monitoring around the clock, from virtually any location. Once the final prototype is completed, the Company contemplates installing units in various settings, including pharmacies, malls, general practices, specialty medical offices, hospitals, emergency rooms, urgent care clinics, nursing homes, and independent living facilities.

The device is easy to operate and does not require a technician or pupil dilation to view a 40° field of vision. It enables remote physicians to access data quickly for immediate assessment. Additionally, the imaging device simultaneously captures retinal and external images of the patient's eye.

A specialized network of retinal specialists will be available to receive the images on a contracted basis, assisting patients who may currently lack an eye care professional to review their results. The device is not intended for diagnostic purposes; rather, it is a screening and monitoring tool. It can lead to immediate resolution, either through a physical examination or by scheduling a prompt visit to a doctor's office.

If necessary, patients may also go directly to the emergency room. The patient's doctor will have control over the patient's disposition, as they will also have immediate access to the device's unique ability to provide real-time information.

"To prevent blindness, triage must occur in real-time, which typically does not happen under current circumstances," says Jerry Katzman, MD, CEO of RetinalGenix Technologies. "Additionally, the device must be available, affordable, accessible, and easy to use."

GROUNDBREAKING PATENTED TECHNOLOGY

The RetinalGeniX™ imaging system is designed to allow routine screenings to be conducted by general practitioners, optometric technicians, clinics, etc., giving highly specialized ophthalmologists and surgeons more time to devote to the most serious patient needs.

Dr. Katzman stated, “Patients should not have to pay $250 to see an eye surgeon for a basic eye screening unless there is a specific reason for it. With the RetinalGeniX system, we intend that patients can be screened by less highly credentialed and more affordable professionals. Highly skilled retinal specialists can then assist in diagnosing conditions once the data is sent to them remotely, ensuring that necessary care is provided when needed.”

Macular degeneration - Truth or Consequences?

Approximately 200 million people worldwide are affected by macular degeneration. The CDC says in the United States, about 10% of these individuals live with the condition. Among them, 90% have the dry type of macular degeneration, while 10% have the wet type. The wet type necessitates treatment involving injections in the eye, which must be administered monthly to quarterly for the rest of the patient's life. These injections can be costly and require a long-term commitment to therapy.

RetinalGenix and Dr. Larry Perich are conducting an IRB approved investigation to correlate genetic markers with the success of intra-ocular injections of monoclonal antibodies to Vascular endothelial growth factor (VEGF), such as Eylea. By doing so, Dr. Perich may be able to establish criteria and guidelines for determining candidate eligibility for these injections. presently, about 25% of patients do not benefit from the therapy as per *The American Journal of Managed Care* July 19, 2019. The findings of this study are expected to aid in the development of a pharmaco-genetic test that eye care professionals can use to predict who will not benefit from the injections. Excluding patients who are unsuitable for the injections and unlikely to benefit, could avoid any unnecessary complications or morbidity while effectively reducing healthcare expenses. The test should be available to patients at a reasonable cost of approximately $355.00. These factors would make the test invaluable.

Over 8 million intraocular injections are performed annually in the United States. That number is growing and according to *Ocular Surgery News* September 25, 2023, is projected to exceed 10 million by 2025. In summary, the RetinalGenix initiative aims to prevent unnecessary treatments and encourage less invasive solutions.

DRY AGE-RELATED MACULAR DEGENERATION (AMD)

The dry type of AMD affects about 18 million people. It can be painful; infections are common and there is no FDA-approved treatment at this time. The RetinalGeniX™ high-resolution retinal imaging system is designed to enable screening for dry macular degeneration in a matter of moments.

A patient with the dry type of age-related macular degeneration (AMD) may have the worst-looking eyes but still maintain the best visual acuity, despite their eye appearance. In contrast, a person may show almost no external signs of macular degeneration and yet experience poor vision. Fortunately, recent evidence suggests that high-resolution imaging, combined with near-infrared and green technology, may provide a solution. The Company believes it has identified a biomarker that could offer an objective way to assess the presence of AMD before any visible signs are detectable by eye care professionals. The biomarker may provide the basis for recognizing the early signs of AMD which the reviewing service would confirm.

The initial step would have the patient get a scan as part of their annual health assessment. The scan may be able to assess the severity of the AMD and whether or not it could rapidly progress to the wet type of AMD.

STRATEGY TO DEVELOP NEW TREATMENTS FOR AMD AND OTHER DISEASES

RetinalGenix also has been implementing its strategy to identify several opportunities to repurpose FDA-approved pharmaceuticals for the potential benefit of Dry AMD, diabetic retinopathy, and dementia. The Company has submitted provisional patents for these indications in the US and Europe.

“We have identified several drugs that we think could be beneficial in various areas of medicine. RetinalGenix has filed patents in the United States and Europe for one of these drugs, which had been extensively studied, but was ultimately abandoned by major pharmaceutical companies. We believe that the ability to use our RetinalGeniX™ imaging system to profile, screen, and monitor patients with AMD and then treat them while monitoring their retina could be the key to effectively managing the dry form of the disease and preventing its progression to the wet form,” continued Dr. Katzman.

The Company believes that in light of the aforementioned groundbreaking breakthroughs and revolutionizing high-resolution advancements, it is poised to be a world leader in the therapeutics, genetic eye care, and systemic disease space.

About RetinalGenix

RetinalGenix is an ophthalmic research and development company focused on developing high-resolution retinal imaging and pharmaco-genetic mapping technologies intended to prevent blindness through the early detection and treatment of ocular diseases and also to detect initial physiological changes that could indicate possible future systemic disease including neurodegenerative, cardiovascular, vascular, metabolic and diabetic conditions.

Safe Harbor Statement

This press release contains certain forward-looking statements within the meaning of the safe harbor provisions of the Private Securities Litigation Reform Act of 1995. These statements are identified by the use of the words “could,” “believe,” “anticipate,” “intend,” “estimate,” “expect,” “may,” “continue,” “predict,” “potential,” “project” and similar expressions that are intended to identify forward-looking statements and include statements regarding further enhancing images from the Company’s first prototype of its device for inclusion in the second prototype, commencing the design for manufacturing, the imaging system enabling secure, real-time remote monitoring around the clock, from virtually any location, installing units in various settings once the final prototype is completed, including pharmacies, malls, general practices, specialty medical offices, hospitals, emergency rooms, urgent care clinics, nursing homes, and independent living facilities, a specialized network of retinal specialists being available to receive the images on a contracted basis, assisting patients who may currently lack an eye care professional to review their results, allowing routine screenings to be conducted by general practitioners, optometric technicians, clinics, etc., establishing criteria and guidelines to correlate genetic markers for determining candidate eligibility for intra-ocular injections of monoclonal antibodies to Vascular endothelial growth factor, the findings of this study aiding in the development of a pharmaco-genetic test that eye care professionals can use to predict who will not benefit from the injections, the test being available to patients at a reasonable cost of approximately $355.00, the test becoming invaluable, preventing unnecessary treatments and encouraging less invasive solutions, enabling screening for dry macular degeneration in a matter of moments, identifying a biomarker that could offer an objective way to assess the presence of AMD before any visible signs are detectable by eye care professionals, the biomarker providing the basis for

recognizing the early signs of AMD which would be confirmed by the reviewing service, identifying opportunities to repurpose FDA-approved pharmaceuticals for the potential benefit of Dry AMD, diabetic retinopathy, and dementia and using the RetinalGenix imaging system to profile, screen and monitor patients with AMD and then treat them while monitoring their retina being the key to effectively managing the dry form of the disease and preventing its progression to the wet form. These forward-looking statements are based on management's expectations and assumptions as of the date of this press release and are subject to a number of risks and uncertainties, many of which are difficult to predict, that could cause actual results to differ materially from current expectations and assumptions from those set forth or implied by any forward-looking statements. Important factors that could cause actual results to differ materially from current expectations include, among others, the Company's ability to successfully complete research and further development and commercialization of Company imaging system or drug candidates, the timing, cost and uncertainty of obtaining regulatory approvals for the Company's imaging system or drug candidates, the Company's ability to protect its intellectual property, and the risk factors described in the Company's Annual Report on Form 10-K for the year the risk factors described in the Company's Annual Report on Form 10-K for the year ended December 31, 2023 and the Company's subsequent filings with the SEC, including subsequent periodic reports on Forms 10-Q and 8-K. The information in this release is provided only as of the date of this release, and we undertake no obligation to update any forward-looking statements contained in this release on account of new information, future events, or otherwise, except as required by law.

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RetinalGeniX™
Home & Remote Monitoring
High-Resolution Retinal Imaging
Drug Validation & Therapeutics
Diagnostic Testing & Therapeutics Testing
DNA/RNA GPS™ Pharmacogenetic Mapping™

Source: RetinalGeniX Technologies, Inc.