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Guardion Health Sciences Initiates Placebo-Controlled Clinical Trial Involving Proprietary GlaucoCetin® Product

Clinical Trial Intended to Demonstrate Improved Visual Function in Glaucoma Patients Taking GlaucoCetin®

SAN DIEGO, May 03, 2021 (GLOBE NEWSWIRE) -- Guardion Health Sciences, Inc. (Nasdaq: GHSI) ("Guardion" or the "Company"), a clinical nutrition and diagnostics company that develops clinically supported nutrition, medical foods, supplements and medical devices, announced the initiation of a placebo-controlled clinical trial to study the impact on visual function, as measured by visual field sensitivity, in patients with glaucoma after a 12-week regimen of GlaucoCetin®.

GlaucoCetin is the Company's proprietary medical food designed to provide support for mitochondrial activity in optic nerve cells. Mitochondrial dysfunction and loss of activity is now thought to be a key factor for vision loss from glaucoma, as well as other common debilitating eye diseases.

The 12-week double-blind study will evaluate 100 patients randomized to receive either GlaucoCetin or a placebo at a 1:1 ratio. Patients will be recruited based on two additional subgroups: those with central vision loss and those with peripheral vision loss. In addition to the primary endpoint of visual field testing, secondary end points include evaluating changes in quality of life, electrophysiology, contrast sensitivity and blood levels of antioxidants, particularly glutathione. Contrast sensitivity is being evaluated using proprietary testing technology from VectorVision, a wholly owned subsidiary of the Company.

"This study, which we are proud to have initiated with one of the leading university-based eye research centers on the East Coast, supports our overall strategy of evaluating the efficacy of our medical foods through rigorously designed clinical studies that demonstrate patient benefits in the real-world," commented David Evans, Ph.D., Guardion's Chief Science Officer.

About Guardion Health Sciences

Guardion Health Sciences, Inc. (Nasdaq: GHSI), is a clinical nutrition and diagnostics company. Guardion offers a portfolio of science-based, clinically supported nutritional supplements, medical foods, and diagnostic products that support healthcare professionals, their patients, and consumers in achieving health goals. Guardion's commercial and developmental initiatives are supported by equally impressive scientific and medical advisory boards, led by seasoned business executives and physicians with many years of experience. This combination of expertise and scientific knowledge forms the foundation of Guardion's growing position within the eye care industry and the clinical nutrition marketplace. Information and risk factors with respect to Guardion and its business, including its ability to successfully develop and commercialize its proprietary products and technologies, may be obtained in the Company's filings with the U.S. Securities and Exchange Commission (the "SEC") at www.sec.gov.

Forward-Looking Statement Disclaimer

With the exception of the historical information contained in this news release, the matters described herein may contain forward-looking statements within the meaning of Section 27A of the Securities Act of 1933, as amended, and Section 21E of the Securities Exchange Act of 1934, as amended. Statements preceded by, followed by or that otherwise include the words “believes,” “expects,” “anticipates,” “intends,” “projects,” “estimates,” “plans” and similar expressions or future or conditional verbs such as “will,” “should,” “would,” “may” and “could” are generally forward-looking in nature and not historical facts, although not all forward-looking statements include the foregoing. These statements involve unknown risks and uncertainties that may individually or materially impact the matters discussed herein for a variety of reasons that are outside the control of the Company, including, but are not limited to, the Company’s ability to raise sufficient financing to implement its business plan, the integration of a new management team, the impact of the COVID-19 pandemic on the Company’s business, operations and the economy in general, the Company’s ability to successfully develop and commercialize its proprietary products and technologies, and the Company’s ability to maintain compliance with Nasdaq’s listing requirements. Readers are cautioned not to place undue reliance on these forward-looking statements, as actual results could differ materially from those described in the forward-looking statements contained herein. Readers are urged to read the risk factors set forth in the Company’s filings with the SEC, which are available at the SEC’s website (www.sec.gov). The Company disclaims any intention or obligation to update or revise any forward-looking statements, whether as a result of new information, future events or otherwise.

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