Eyenovia & SGN Nanopharma Announce Collaboration Agreement to Develop Novel Treatment for Chronic Dry Eye Disease

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The U.S. addressable market for Dry Eye Disease is valued at over $3 billion by independent sources

NEW YORK, July 30, 2024 (GLOBE NEWSWIRE) -- Eyenovia, Inc. (NASDAQ: EYEN), a commercial-stage ophthalmic company with two FDA-approved products and a late-stage asset in pediatric progressive myopia, and SGN Nanopharma, today announced that the companies have entered into a collaboration agreement to develop a treatment for chronic dry eye disease.

Under the terms of the agreement, the companies will work to develop SGN's Micellar Nanoparticle Platform (MNP) platform-based cyclosporine formulation for use with Eyenovia's Optejet ® dispenser. The companies are currently validating the novel drug-device combination product's manufacturability to support clinical testing and will then schedule a consultation meeting with the FDA to discuss clinical development.

It has been estimated by independent sources that as many as 35 million people are affected by dry eye disease in the U.S., including 1/3 of all diabetics. Of these, approximately 16 million have been formally diagnosed. The current standard of care treatment for dry eye is cyclosporine, an immune inhibitor that makes it easier for the body to produce tear fluid by inhibiting the underlying inflammation. Dry eye represents an approximate $3 billion addressable market annually in the U.S., of which approximately $2.35 billion is derived from sales of cyclosporine-based therapeutics.

"Our MNP Cyclosporine was shown to be statistically superior in a head-to-head clinical study versus the current standard of care. The data demonstrates the efficacy of MNP Cyclosporine in as little as four weeks and a lower incidence of side effects such as corneal irritation," stated Dr. Navdeep Jaikaria, Chairman & Chief Executive Officer of SGN Nanopharma. "With the precision dosing afforded by the Optejet dispenser, we believe we can further improve this promising drug's efficacy and tolerability profile. Our 'drug-device' combination therapy with Eyenovia has the potential to be the 'best-in-class' and to significantly improve patient outcomes and market penetration in this highly underserved dry eye market. We look forward to working with our partners at Eyenovia, and our investors toward this goal."

"Notwithstanding the widespread use of cyclosporine-based treatments for dry eye disease, currently available formulations have significant shortcomings, including a delayed onset of action of up to 12 weeks and unpleasant side effects that result in significant patient attrition and non-compliance," stated Michael Rowe, Chief Executive Officer of Eyenovia. "The Optejet dispenser has been shown in prior studies to deliver a therapeutic dose of medication with 80% less drug volume, thereby minimizing exposure to harmful preservatives and improving tolerability. We believe the power of SGN's MNP platform, when combined with the Optejet, will result in a more efficacious and better tolerated cyclosporine-based treatment that we believe has the potential to become the standard of care in this multi-billion-dollar addressable market."

About Eyenovia, Inc.

Eyenovia, Inc. (NASDAQ: EYEN) is a commercial-stage ophthalmic pharmaceutical technology company developing a pipeline of microdose array print therapeutics. Eyenovia is currently focused on the commercialization of MYDCOMBI® for mydriasis, clobetasol propionate ophthalmic suspension, 0.05% for post-surgical pain and inflammation, as well as the ongoing late-stage development of medications in the Optejet device for pediatric progressive myopia as well as out-licensing for additional indications. For more information, visit Eyenovia.com.

The Eyenovia Corporate Information slide deck may be found at ir.eyenovia.com/events-and-presentations.

PLEASE GO TO MYDCOMBI.COM FOR IMPORTANT SAFETY INFORMATION for MYDCOMBI™ (tropicamide and phenylephrine hydrochloride ophthalmic spray) 1%/2.5%

PLEASE GO TO CLOBETASOLBID.COM FOR IMPORTANT SAFETY INFORMATION for Clobetasol Proprionate Ophthalmic Suspension 0.05%

About SGN Nanopharma, Inc.

SGN Nanopharma (https://sgnnanopharma.com/) is an innovation-led, clinical-stage, nanopharmaceutical company focused on creating impactful, best-in-class nanotherapeutics targeting large unmet medical needs while reducing the cost and time to commercialization. Chronic diseases continue to be underserved by the current, prevalent mono-therapeutic approaches (which are partially effective at best), creating persisting unmet medical needs. Our objective is to select for and bring to market clinically differentiated, superior combination nanomedicines that mitigate unmet medical needs in large therapeutic areas to create maximal patient impact.

Forward-Looking Statements

Except for historical information, all the statements, expectations and assumptions contained in this press release are forward-looking statements. Forward-looking statements include, but are not limited to, statements that express our intentions, beliefs, expectations, strategies, predictions or any other statements relating to our future activities or other future events or conditions, including estimated market opportunities for our product candidates and platform technology, and the timing for availability and sales growth of our approved products. These statements are based on current expectations, estimates and projections about our business based, in part, on assumptions made by management. These statements are not guarantees of future performance and involve risks, uncertainties and assumptions that are difficult to predict. Therefore, actual outcomes and results may, and in some cases are likely to, differ materially from what is expressed or forecasted in the forward-looking statements due to numerous factors discussed from time to time in documents which we file with the U.S. Securities and Exchange Commission.

In addition, such statements could be affected by risks and uncertainties related to, among other things: risks of our clinical trials, including, but not limited to, the costs, design, initiation and enrollment, timing, progress and results of such trials; the timing of, and our ability to submit applications for, obtaining and maintaining regulatory approvals for our products and product candidates; the potential advantages of our products, product candidates and platform technology; the rate and degree of market acceptance and clinical utility of our products and product candidates; our estimates regarding the potential market opportunity for our products and product candidates; reliance on third parties to develop and commercialize our products and product candidates; the ability of us and our partners to timely develop, implement and maintain manufacturing, commercialization and marketing capabilities and strategies for our products and product candidates; intellectual property risks; changes in legal, regulatory, legislative and geopolitical environments in the markets in which we operate and the impact of these changes on our ability to obtain regulatory approval for our products and product candidates; and our competitive position.

Any forward-looking statements speak only as of the date on which they are made, and except as may be required under applicable securities laws, Eyenovia does not undertake any obligation to update any forward-looking statements.

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