Eyenovia and Senju Pharmaceutical Co., Ltd. Sign Collaboration Agreement for Potential New Treatment for Chronic Dry Eye Disease

July 23, 2024 at 7:00 AM EDT

Collaboration to focus on the development of a formulation of Senju's SJP-0035 for use with Eyenovia's Optejet ® dispensing technology, following consultation with FDA

Chronic dry eye estimated to be a $5 billion global addressable market

NEW YORK, July 23, 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, today announced that it has entered into a collaboration agreement with Senju Pharmaceutical Co., Ltd. (Senju), under which both companies intend to work to develop Senju's corneal epithelial wound healing candidate, SJP-0035, for use with Eyenovia's Optejet ® dispensing technology, as a potential treatment for chronic dry eye disease.

Per the terms of the agreement, Eyenovia and Senju are planning to meet with the U.S. Food and Drug Administration (FDA) to present a clinical development proposal that, if successful, could support a New Drug Application (NDA) filing for a novel drug-device combination product for the treatment of chronic dry eye disease. Nearly sixteen million Americans suffer from dry eye, with the cost of treatments totaling over $3 billion in the U.S. alone, and $5 billion globally.

SJP-0035 as an eye drop has been shown in prior Phase 1 and Phase 2 studies to be well tolerated at multiple doses tested in over 250 subjects. A planned Phase 2b trial would evaluate SJP-0035 administered in the Optejet dispenser.

"We are very pleased to further leverage our proprietary Optejet platform through this collaboration agreement with Senju, a global leader in eye care that has been part of the Eyenovia family since our inception," stated Michael Rowe, chief executive officer of Eyenovia. "Symptoms of dry eye can interfere significantly with many aspects of daily life, and patients are often unsatisfied with current therapies. According to a recent survey, 48% of dry eye patients reported following their treatment plans carefully, yet just 13% experienced lasting relief[1]. We believe this product, if approved, has the potential to be used together with other therapies to better address the most debilitating symptoms of dry eye, a multi-billion-dollar addressable market, and we look forward to engaging with the FDA to outline an efficient path forward."

"SJP-0035 has a unique mechanism of action that has the potential to offer dry eye patients additional relief when compared to existing treatment options alone, while also demonstrating a very favorable tolerability profile," said Mitsuyoshi Isaka, a corporate executive officer of Senju. "When integrated with a novel dosing platform such as the Optejet, we believe we can create a more efficacious and highly differentiated treatment that could quickly become the new standard of care for this very prevalent ophthalmic condition. We look forward to a long and mutually successful partnership."

The companies anticipate a meeting with the FDA later this year, to be followed by execution of a definitive agreement relating to further development of SJP-0035 and anticipated completion of a Phase 2b study in 2025. If successful, the companies could expand upon their collaboration agreement to bring the product into two Phase 3 studies by 2026.

About Senju Pharmaceutical Co., Ltd.
Senju is a privately held, research-based Japanese pharmaceutical company that develops, manufactures, and commercializes a variety of innovative products, focusing on the field of ophthalmology to improve the health and quality of vision for people worldwide.

The characters that comprise Senju's company name in the Japanese language are "Sen" and "Ju", or "thousand" and "bringing happiness". Senju's mission is to improve the joy of living of people associated with the company through the development of original pharmaceutical products.

Senju is headquartered in Osaka, Japan, and has its subsidiaries and representative offices around the world. More on www.senju.co.jp/english/.

About Eyenovia, Inc.
Eyenovia, Inc. (NASDAQ: EYEN) is an ophthalmic technology company commercializing Mydcombi™ (tropicamide and phenylephrine hydrochloride ophthalmic spray) 1%/2.5% for mydriasis, clobetasol propionate ophthalmic suspension, 0.05% for postsurgical inflammation and pain, and developing the Optejet® device for use both in connection with its own drug-device therapeutic product 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.

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 the outcome of regulatory discussions and negotiations for a definitive agreement relating to the development of SJP-0035, 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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IMPORTANT SAFETY INFORMATION: Clobetasol Propionate Ophthalmic Suspension 0.05% is indicated for the treatment of post-operative inflammation and pain following ocular surgery. **CONTRAINDICATIONS:** Most active viral diseases of the cornea and conjunctiva, including epithelial herpes simplex keratitis (dendritic keratitis), vaccinia, and varicella, and also in mycobacterial infection of the eye and fungal diseases of ocular structures. **WARNINGS AND PRECAUTIONS:** Intraocular Pressure (IOP) Increase: Prolonged use of corticosteroids may result in glaucoma with damage to the optic nerve, defects in visual acuity and fields of vision. Steroids should be used with caution in the presence of glaucoma. If this product is used for 10 days or longer, IOP should be monitored. Cataracts: Prolonged use of corticosteroids may result in posterior subcapsular cataract formation. Delayed Healing: The use of steroids after cataract surgery may delay healing and increase the incidence of bleb formation. Corneal and Scleral Melting: In those diseases causing thinning of the cornea or sclera, perforations have been known to occur with the use of topical steroids. The initial prescription and renewal of the medication order should be made by a physician only after examination of the patient with the aid of magnification, such as slit lamp biomicroscopy, and where appropriate, fluorescein staining. Bacterial Infections: Prolonged use of corticosteroids may suppress the host response and thus increase the hazard of secondary ocular infections. In acute purulent conditions, steroids may mask infection or enhance existing infection. If signs and symptoms fail to improve after 2 days, the patient should be reevaluated. Viral Infections: Employment of a corticosteroid medication in the treatment of patients with a history of herpes simplex requires great caution. Use of ocular steroids may prolong the course and may exacerbate the severity of many viral infections of the eye (including herpes simplex). Fungal Infections: Fungal infections of the cornea are particularly prone to develop coincidentally with long-term local steroid application. Fungus invasion must be considered in any persistent corneal ulceration where a steroid has been used or is in use. Fungal culture should be taken when appropriate. **ADVERSE REACTIONS:** Ocular adverse reactions occurring in ≥ 1% of subjects in clinical studies who received clobetasol propionate ophthalmic suspension 0.05% included eye inflammation (2%), corneal edema (2%), anterior chamber inflammation (2%), cystoid macular edema (2%), intraocular pressure elevation (1%), photophobia (1%) and vitreous detachment (1%). Many of these reactions may have been the consequence of the surgical procedure. **PLEASE GO TO CLOBETASOLBID.COM FOR FULL PRESCRIBING INFORMATION**

IMPORTANT SAFETY INFORMATION: MYDCOMBI (tropicamide 1% and phenylephrine HCl 2.5%) ophthalmic spray is indicated to induce mydriasis for routine diagnostic procedures and in conditions where short term pupil dilation is desired.
CONTRAINDICATIONS: Known hypersensitivity to any component of the formulation. **WARNINGS AND PRECAUTIONS:** Not for Injection: Topical ophthalmic use. Significant Elevations in Blood Pressure: Caution in pediatric patients less than 5 years of age, and in patients with cardiovascular disease or hyperthyroidism. In patients at high risk, monitor blood pressure post treatment. Central Nervous System Disturbances: Caution in pediatric patients where rare incidences of central nervous system disturbances have been reported. Intraocular Pressure: May produce a transient elevation. Rebound Miosis: Reported 1 day after administration. **DRUG INTERACTIONS:** Atropine-like Drugs: May exaggerate the adrenergic pressor response. Cholinergic Agonists and Ophthalmic Cholinesterase Inhibitors: May interfere with the antihypertensive action of carbachol, pilocarpine, or ophthalmic cholinesterase inhibitors. Potent Inhalation Anesthetic Agents: May potentiate cardiovascular depressant effects of some inhalation anesthetic agents. **ADVERSE REACTIONS**: Most common ocular adverse reactions include transient blurred vision, reduced visual acuity, photophobia, superficial punctate keratitis, and mild eye discomfort. Increased intraocular pressure has been reported following the use of mydriatics. Systemic adverse reactions including dryness of the mouth, tachycardia, headache, allergic reactions, nausea, vomiting, pallor, central nervous system disturbances and muscle rigidity have been reported with the use of tropicamide. To report **SUSPECTED ADVERSE REACTIONS**, contact Eyenovia, Inc. At 1-833-393-6684 or FDA at 1-800-FDA-1088 www.fda.gov/medwatch

[1] https://www.aao.org/eye-health/tips-prevention/fix-dry-eye-treatment-eyedrops

Source: Eyenovia, Inc.