Trefoil Therapeutics Raises $28 Million Series A to Advance Engineered FGF-1 for the Treatment of Corneal Diseases

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Lead candidate TTHX1114 will advance to IND and clinical study in corneal endothelial disease in early 2020

SAN DIEGO, July 16, 2019 (GLOBE NEWSWIRE) -- Trefoil Therapeutics announced it raised $28 million in an oversubscribed Series A financing. The company is developing novel engineered fibroblast growth factor-1 proteins (eFGF-1) as a regenerative pharmacologic therapy to treat serious corneal endothelial diseases and epithelial disorders. The financing included new investors Bios Partners, which led the round, and Access Biotechnology. All existing investors, including Hatteras Venture Partners, Aju IB Investment, Correlation Ventures, ExSight Ventures and InFocus Capital Partners, participated in this financing. Stella M. Robertson, Ph.D., co-founder of Bios Partners, and a former vice president in Research & Development at Alcon Laboratories, will join Trefoil's Board of Directors.

Trefoil's lead candidate TTHX1114 is an engineered form of the FGF-1 protein designed to reverse vision loss by stimulating endothelial cell proliferation and migration. Preclinical data has demonstrated TTHX1114's ability to accelerate corneal clearing in animal models of corneal endothelial dystrophy and enhance healing in corneal chemical injury and herpetic keratopathy. In human cornea organ culture models, TTHX1114 stimulates the proliferation and migration of endothelial tissue in both normal and diseased corneas, addressing the key defect in corneal endothelial dystrophies.

This funding supports the completion of a Phase 2a proof-of-concept study in corneal endothelial dystrophy, including Fuchs dystrophy, a disease which leads to the deterioration of the endothelial layer on the back surface of the cornea. Trefoil anticipates filing an Investigational New Drug (IND) application with the U.S. Food and Drug Administration (FDA) in early 2020 and initiating the clinical trial soon thereafter.

"Therapeutic options for endothelial corneal diseases are limited aside from cornea transplant surgery, which is invasive, expensive and may require life-long steroid use for immunosuppression," said Richard L. Abbott, M.D., Professor Emeritus, Cornea and External Diseases, UCSF Department of Ophthalmology, and Research Associate, Francis I. Proctor Foundation. "Fuchs dystrophy and other corneal endothelial diseases are among the leading causes of corneal transplantation. There is a high unmet need for a pharmacologic option that would allow treatment of these diseases earlier and potentially reduce or eliminate the need for surgical intervention."

The funding also enables Trefoil to move forward with IND-enabling studies of a topical formulation of TTHX1114 for the treatment of ulcerative conditions of the cornea, with a planned submission of a second IND for corneal epithelial conditions in 2021.

“Trefoil is developing TTHX1114 with the goal of providing the first regenerative therapeutic agent for the treatment of corneal dystrophy to reverse the vision loss associated with these conditions without the need for surgery for many patients,” said David Eveleth, Ph.D., Co-Founder and Chief Executive Officer of Trefoil. “We are grateful to our new and existing investors, who recognize the opportunity we have to make a meaningful difference in the lives of people with sight-destroying corneal diseases and conditions. We look forward to initiating our first clinical study early next year.”

“Trefoil’s regenerative approach offers a promising opportunity to develop first-in-class pharmacologic treatments for corneal diseases,” said Dr. Robertson. “With its strong scientific foundation, compelling preclinical data and leadership team’s depth of experience in ophthalmic drug development, Trefoil is well-positioned to bring these therapies to market. We are pleased to support Trefoil at this pivotal time.”

About Trefoil Therapeutics

Trefoil Therapeutics is a private biotechnology company focused on leveraging its engineered fibroblast growth factor-1 protein (eFGF-1) technology platform to develop first-in-class pharmacologic treatments for serious corneal endothelial diseases and epithelial disorders. Trefoil’s lead product candidate is TTHX1114, an engineered form of FGF-1 designed to reverse vision loss by stimulating cell proliferation and migration. The technology underlying Trefoil’s platform was developed by co-founder Michael Blaber, Ph.D., and is licensed from Florida State University. For more information, visit **www.trefoiltherapeutics.com (https://www.globenewswire.com/Tracker?data=L3R9t3u80GhU40xOJS-9GOK1wUKKUERktlCQKOvnQfmiIG2mIQVhEuKdBMYWK-uOjZu1nXdShmnUYDm5SAyrEuo3W00Nq427Z1GXMu8N5rpxX5kg4GdMdL-ZtZjosMxM)**.

About Bios Partners

Bios Partners is a venture capital firm focused on investing in early-stage biopharmaceutical and medical device companies. Founded in 2014 and based in Fort Worth, TX, the firm utilizes an experienced team of industry professionals to actively collaborate with its investment portfolio companies and enhance stakeholder value. For more information, please visit **https://www.biospartners.com (https://www.globenewswire.com/Tracker?data=BMgN7qjYopptWhC3_-Hhjo8y7nl_Nc8lXvoacJyCLXjqOGPuLJoe8AGXsxp3X_RacCP6GGL-rcamgM8N99-I4TxTfF4yDmfY9j1abddqehY=)**.

Safe Harbor Statement

The preclinical research discussed in this press release is preliminary and the outcome of such preclinical studies may not be predictive of the outcome of later clinical trials. Future clinical trial results may not demonstrate safety and efficacy sufficient to obtain regulatory approval related to the preclinical research findings discussed in this press release.

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