

Trefoil Therapeutics Announces Completion of Pre-IND Meeting with FDA for TTHX-1114 for the Treatment of Corneal Endothelial Dystrophies

Guidance Provides a Clear Path for the Filing of an IND and Clinical Proof of Concept Studies

San Diego — Trefoil Therapeutics, an early stage biopharmaceutical company focused on developing a regenerative approach to corneal endothelial dystrophies and other diseases based on novel engineered derivatives of fibroblast growth factor-1 (eFGF-1) announced completion of a pre-IND meeting with the FDA that took place on January 20 regarding Trefoil's lead product candidate, TTHX-1114 for the treatment of Bullous Keratopathy and Fuchs Dystrophy, diseases that are currently treated by corneal transplantation.

The purpose of the meeting was to obtain guidance from the FDA on for the path to an IND filing for TTHX-1114 in the US and the clinical development program. The discussions included manufacturing criteria, the scope and design of the preclinical studies, and the scope and design of Trefoil's first in human and proof of concept (phase I/II) clinical trials. The FDA also provided feedback and clarity on elements of the future pivotal phase III trials.

David Eveleth, PhD, CEO, noted, "We were encouraged by the FDA's feedback and comments and now have a clear path to the clinic as well as guidance on the FDA's expectations for approval. Trefoil is on schedule to file an IND in 2017 with the first clinical studies planned immediately upon approval of the IND."

"We are very excited about the potential for this innovative treatment to either eliminate or delay the need for corneal transplantations procedures in patients who currently have no therapeutic option other than corneal transplantation," says William Trattler, MD, Director Cornea Service at the Center for Excellence in Eye Care, Miami, Florida. "TTHX-1114 would provide the first pharmaceutical therapeutic option for these debilitating corneal diseases."

About Trefoil:

Trefoil's mission is to improve human health and create new therapies using drugs developed with protein engineering. Trefoil hopes to bring this novel therapy into clinical testing within 18 months. Other potential applications for the eFGFs include regenerative therapies that may address a broad range of ischemic disease, including coronary heart disease, dermal ulcers, and peripheral artery disease.

Trefoil has received several accolades including winning the CONNECT Springboard business plan program (2013) and the Southeast Biotechnology Early Company Competition (2014).

Forward-Looking Statements

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.

For information contact:
Dr. David Eveleth, CEO
develeth@trefoiltherapeutics.com
917 628 8502

www.trefoiltherapeutics.com