SilkTech Biopharmaceuticals’ IND Submission Cleared by FDA; Phase 2 Clinical Trial Initiated for Patients with Dry Eye Disease

*Milestone Results in $6.2 Million in Additional VC Funding*

MINNEAPOLIS and LOS ANGELES (PRWEB) April 16, 2019 -- SilkTech Biopharmaceuticals, a company devoted to improving eye health through the development of silk-derived protein biotherapeutics for the targeted treatment of Dry Eye Disease (DED), today announced the company has received clearance of its Investigational New Drug (IND) submission with the U.S. Food and Drug Administration (FDA) for its SDP-4 eye drop product. In addition, the company has initiated a Phase 2 clinical trial for its first-in-class drug to assess the safety and efficacy of the use of the product in treating the signs and symptoms of DED.

“We are proud to have initiated what we believe to be the first human clinical trial to assess a silk-derived protein biologic drug for treating an ophthalmic condition. And we are especially excited to have the opportunity to assess the impact of this compound in patients who suffer from the debilitating effects of DED,” said CEO and co-founder Brian D. Lawrence, Ph.D.

With the IND submission clearance, SilkTech has reached a new milestone that brings the company an additional $6.2 million in available venture financing from Skyview Ventures (Los Angeles, CA) to support the Phase 2 clinical trial and ongoing development work. The total available Series A funding is $11.2 million. “As a patient who himself suffers from Dry Eye, I could not be more enthusiastic about seeing this novel therapeutic entering the clinic,” said Alex Soltani, CEO of Skyview and a member of the SilkTech board of directors. “As an investment partner, we believe this technology could represent a paradigm shift in the treatment of this disease.”

**About the SDP-4 Eye Drop**

SDP-4 offers a novel biotherapeutic approach that uses a naturally derived silk protein to treat DED through a dual-mechanism of action. It has been designed to inhibit the inflammatory mediators that may promote the symptoms of DED. Additionally, since SDP-4 is a protein in nature, the design of the eye drop formulation is intended to utilize the inherent spreading and wetting properties that a soluble protein may impart on the eye’s surface to stabilize the tear film and potentially improve physical comfort. The eye drop is supplied in single-unit dose containers as a preservative free, water-based formulation that is stored at room temperature.

“The SDP-4 eye drop is designed to utilize an innovative biologic approach to dealing with the inflammation and tear film instability that occurs in patients suffering from Dry Eye Disease,” said Dr. Edward Holland of the Cincinnati Eye Institute and a globally recognized expert in DED.

**About Dry Eye Disease (DED)**

It is believed that up to 340 million people suffer from Dry Eye Disease (DED) worldwide. In the U.S., nearly 16 million patients are estimated to have been diagnosed with DED. An additional 30 to 40 million individuals may remain undiagnosed and could benefit from therapeutic treatment. DED is a disorder of the tear film that can lead to ocular surface damage and create discomfort for the patient. When compromised, the tear film may leave portions of the ocular surface uncovered, or cause tears to become unhealthy in composition. This can be caused by a number of irritating effects, which may be environmental or physiological in nature. Continued irritation to the ocular surface can create inflammation that over time may further destabilize the tear film and potentially worsen patient symptoms. SDP-4 is designed to counteract these effects by working to
simultaneously stabilize the tear film with protein, while inhibiting inflammation that may cause DED symptoms.

About the Phase 2, or SDP-4-CS201, Clinical Trial
The Phase 2 clinical trial (SDP-4-CS201) is a 300-patient, multi-center, double- masked, randomized, vehicle-controlled, dose-response, parallel-group study designed to evaluate the ocular safety and efficacy of SDP-4 ophthalmic solution in subjects with moderate to severe dry eye disease over a 12-week treatment period. Three concentrations (0.1%, 1.0%, and 3.0%) of SDP-4 ophthalmic solution will be given to parallel groups via topical ocular instillation dosed twice per day. The objective of this study is to meet a primary symptom improvement endpoint as evaluated using the SANDE questionnaire, with additional secondary sign and symptom endpoints included. Topline results from this study are expected in late 2019 and will be used to inform the design of future Phase 3 studies.

About SilkTech Biopharmaceuticals
SilkTech Biopharmaceuticals, founded in 2013 and based in the Minneapolis suburb of Plymouth MN, is a privately held corporation that is a leading developer of silk-based biotherapeutic technologies. The company is devoted to transforming the treatment of DED through the use of its patented silk-derived protein (SDP) technology, which is produced from the naturally occurring Bombyx mori silkworm cocoon. Please visit www.silk-tech.com for the latest information and company development updates.

IMPORTANT NOTICE: SDP-4 is an investigational new drug. SDP-4 has not been approved by the US Food and Drug Administration (FDA) for safety or effectiveness. The FDA has not approved SDP-4 for use. No clinical testing results have shown that SDP-4 is safe or effective.
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