## Seikagaku Initiates a Phase II/III Clinical Trial for SI-614, Indicated for Treatment of Dry Eye, in the U.S.

Seikagaku Corporation (Tokyo, Japan) hereby announces the start of a Phase II/III clinical trial in the U.S for SI-614, indicated for treatment of dry eye.

Based on the clinically meaningful results of the phase II study, the phase II/III, multicenter, randomized, double-masked, placebo-controlled study will be conducted to evaluate the efficacy and safety of SI-614 and accumulate further data in patients with dry eye.

It has been estimated that more than 20 million people suffer from dry eye in the U.S., and the number of patients with moderate to severe dry eye is thought to be approximately 4.9 million. Seikagaku expects to contribute to a healthier and more fulfilling quality of life for patients by providing a novel and safer therapeutic option for the treatment of dry eye.

<SI-614 for the treatment of dry eye>

Dry eye is a chronic disease accompanied by ocular discomfort and visual disturbance, and it is thought to be caused by dryness and irritation of the ocular surface resulting from a lack of tears or changes due to overuse of the eyes or aging, etc.

SI-614 is a modified hyaluronate using Seikagaku's proprietary technology. Ocular instillation of SI-614 is expected to improve accompanied symptoms found in dry eye patients by protecting the ocular surface and promoting corneal epithelial wound healing in dry eye patients.

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