May 13, 2022

SEIKAGAKU CORPORATION
(Securities Code: TSE 4548)

Seikagaku Initiates a Phase III Clinical Study for SI-614, a Therapeutic Agent for Dry Eye, in the U.S.

Seikagaku Corporation (Tokyo, Japan; “Seikagaku”) announced today that it has initiated a Phase III clinical study in the U.S. for SI-614, ophthalmic solution for treatment of dry eye.

Clinically beneficial effects were confirmed in Phase II/III clinical study. Accordingly, Seikagaku will evaluate the efficacy and safety of SI-614 in a multicenter, randomized, double-blind, placebo-controlled Phase III clinical study.

SI-614 is an amphiphilic[1] polymer produced by introducing a hydrophobic group[2] into hyaluronic acid using Seikagaku’s own proprietary technology. Ocular instillation of SI-614 in dry eye patients is thought to stabilize the tear film by utilizing the mucoadhesive and surface tension reducing properties of SI-614 and to promote corneal epithelial wound healing by binding SI-614 to the fibronectin[3] that occurs on corneal epithelial defects to promote epithelial cell growth. Through these actions, SI-614 is expected to restore the tear film and corneal structure to their normal state and improve symptoms associated with dry eye.

Dry eye is a chronic disease accompanied by ocular discomfort and visual disturbance that is caused by dryness and irritation of the ocular surface resulting from a decrease in tear production or changes in tear composition due to overuse of the eyes or aging, etc.

In the U.S., it is estimated that approximately 14 million people[4] suffer from dry eye. Seikagaku aims to contribute to improved quality of life for patients by providing a therapeutic option for dry eye based on a new mechanism of action not available in existing products.

Reference Information

1 Amphiphilic: The property of showing affinity for (tendency to bind with) both water and oil
2 Hydrophobic group: A modifying group that doesn’t blend with water, but blends well with oil
3 Fibronectin: A protein that attaches cells to the extracellular matrix
4 Global Data: Dry Eye Syndrome – Global Drug Forecast and Market Assessment to 2024

< Cautionary Notes >

This press release contains forward-looking statements regarding future management strategies and performance forecasts. These descriptions are based on judgments derived from information that is currently available to Seikagaku and are subject to risk and uncertainty. Actual results and developments may differ significantly from these descriptions due to various factors. Information about pharmaceutical products or medical devices (including products currently in development) contained in this press release is not intended to constitute an advertisement or medical advice.

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