## Seikagaku Initiates a Phase II Clinical Trial in the United States for SI-614, Indicated for Treatment of Dry Eye

Tokyo, Japan, January, 2012—Seikagaku Corporation (hereafter "Seikagaku") (head office: Chiyoda-ku, Tokyo) hereby announces that SI-614 has entered into a Phase II clinical trial in the United States (U.S.) for the treatment of dry eye.

Dry eye is a chronic disease accompanied with ocular discomfort and visual disturbance. Dry eye is thought to be caused by the tear film instability and damage of the ocular surface resulting from a lack of tears or change in tear film quality due to multiple factors such as overuse of the eyes or aging. In the U.S., more than 20 million people are estimated to suffer from dry eye, and the number of patients with moderate to severe dry eye is approximately 4.9 million.

SI-614 is a modified hyaluronate with an excellent tear film stabilizing effect that is produced by Seikagaku's proprietary technology. Ocular instillation of SI-614 is expected to improve the tear film instability of the three layers (lipid layer, aqueous layer, and mucin layer) and accompanied symptoms found in dry eye patients.

Seikagaku specializes in research and development in glycoscience and engages in efficient R&D activities. SI-614 is a development program related to the field of ophthalmology, which Seikagaku has designated as one of the high-priority disease field. Through the development of SI-614, Seikagaku expects to contribute to more healthy and fulfilling quality of life of patients by providing a new therapeutic option for the treatment of dry eye.

## Reference Information

## Tear Film

The tear film, which has the function of protecting the cornea, consists of three

layers: lipid, aqueous, and mucin. A deficiency of any of these components results in the loss of normal ability to retain the tear film, which is said to cause dry eye.

- Lipid (oil) layer: A layer that covers the aqueous layer to prevent it from evaporating
- Aqueous (water) layer: A layer that contains large quantities of oxygen and nutrients supplied to the cornea and accounts for most of the tear volume
- Mucin layer: A viscoelastic foundation layer that anchors the other two layers to the eye surface

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