

## **Seikagaku Initiates a Phase I/II Clinical Study for SI-722 in the U.S., an Indication for Interstitial Cystitis and Bladder Pain Syndrome**

Seikagaku Corporation (Tokyo, Japan; “Seikagaku”) announced today that it has initiated a Phase I/II clinical study in the U.S. for SI-722, a therapeutic agent for interstitial cystitis and bladder pain syndrome (IC/BPS).

IC/BPS is an intractable condition whose primary symptoms are frequent urination and bladder pain and is often seen in middle- and advance-age women. In the U.S., it is estimated that 1.3 million people suffer from IC/BPS. A clear cause of the disease has not been identified yet, and given the repeated remission and recurrence, medical care must be administered over a long period. As a result, the quality of life of patients can be greatly impaired.

SI-722 is a novel chemical compound in which a steroid is conjugated with chondroitin sulfate using Seikagaku's proprietary glycosaminoglycan (GAG)<sup>\*1</sup> modification technology and drug delivery systems (DDS)<sup>\*2</sup>. We believe that intravesically instilled SI-722 provides sustained release<sup>\*3</sup> of the steroid having anti-inflammatory activity resulting in a demonstration of long-lasting improvement in the conditions of frequent urination and bladder pain..

Seikagaku is engaged in the research and development of new products with a focus on the field of glycoscience. The company follows a drug discovery approach of increasing the bioactivity of GAG, mainly through GAG modification and processing, and is currently applying GAG to DDS. SI-722 provides new options for the treatment of IC/BPS and may contribute to a healthy and fulfilling quality of life for patients.

### < Reference Information >

\*1 Glycosaminoglycans (GAGs) are major components of glycoconjugates. Chondroitin sulfate and hyaluronic acid are GAGs.

\*2 Drug delivery system (DDS) is a technology for the controlled release, targeting, and absorption improvement of drugs.

\*3 Sustained release is the gradual release of the active pharmaceutical ingredients of a drug.

### <Cautionary Notes>

This press release contains forward-looking statements regarding future management strategies or 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) included in this press release is not intended to constitute an advertisement or medical advice.

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