

December 25, 2012
Seikagaku Corporation
(Securities Code: 4548)
Kaken Pharmaceutical Co., Ltd.
(Securities Code: 4521)

Seikagaku and Kaken Conclude an Exclusive Distributorship Agreement for SI-6603, Indicated for Treatment of Lumbar Disc Herniation, in Japan

Seikagaku Corporation (Tokyo) and Kaken Pharmaceutical Co., Ltd. (Tokyo) hereby announce that today they have concluded an agreement concerning exclusive marketing rights in Japan for SI-6603, indicated for treatment of lumbar disc herniation. The agreement is based on the basic distributorship agreement executed on May 10, 2012.

Seikagaku is conducting clinical development of SI-6603 in Japan and the U.S. In Japan, the Phase III clinical development is progressing smoothly, and Seikagaku aims to apply for Marketing Approval during the fiscal year ending March 31, 2014.

Characteristics of SI-6603

Lumbar disc herniation is the partial protrusion of the nucleus pulposus at the core of each intervertebral disc or the anulus fibrosus, the disc's outer layer. The resulting pressure on the spinal nerve root causes, pain and numbness. SI-6603 is an enzyme named condoliase that specifically degrades glycosaminoglycans (GAG), which are the main components of the nucleus pulposus. An injection of SI-6603 into the intervertebral disc would cause reduction of the pressure on the nerves by shrinking nucleus pulposus through degrading GAG, resulting in relief from pain. Because SI-6603 does not break down proteins, it is thought to have no effect on surrounding tissues such as nerves.

Since currently no fundamental pharmacological therapy for lumbar disc herniation exists, the launch of SI-6603, of which a single injection treatment is expected to be as effective as lumbar disc surgery in improving symptoms, is expected to contribute to the alleviation of the patient's physical load and reduced medical costs, including surgical and hospitalization costs.

In the U.S., Seikagaku has completed a Phase II clinical trial and is making preparations for a Phase III clinical trial.

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