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Seikagaku Corporation
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Seikagaku Initiates a Phase III Clinical Trial for SI-6603, Indicated for Treatment of Lumbar Disc Herniation, in the U.S.

Seikagaku Corporation (Tokyo) hereby announces the start of a Phase III clinical trial for SI-6603 (generic name: condoliase), indicated for treatment of lumbar disc herniation, in the U.S.

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 injectable drug using an enzyme named condoliase that specifically degrades glycosaminoglycans (GAG), which are the main components of the nucleus pulposus. A direct injection of SI-6603 into the intervertebral disc would cause reduction of the pressure on the nerves by shrinking the 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 blood vessels and nerves.

Approximately three million people in the U.S., about 1% of the population, are estimated to be affected by lumbar disc herniation with an especially high number of males from their 20s to 40s. Since currently no fundamental pharmacological therapy for lumbar disc herniation exists, the launch of SI-6603, of which a single injection treatment is thought 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.

The Phase III trial in Japan is progressing smoothly and the case registration has already been completed. By focusing on development of SI-6603 in preparation for obtaining early approval in Japan and the U.S. and providing a new therapeutic option for the treatment of lumbar disc herniation, Seikagaku aims to contribute to more healthy and fulfilling quality of life in patients.

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