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SEIKAGAKU CORPORATION
(Securities Code: TSE 4548)
Kaken Pharmaceutical Co., Ltd.
(Securities Code: TSE 4521)

Seikagaku and Kaken Announce the Listing in the National Health Insurance Drug Price List and Launch Date of HERNICORE® 1.25 Units for Intradiscal Injection in Japan, Indicated for Treatment of Lumbar Disc Herniation

Seikagaku Corporation (Tokyo, Japan; “Seikagaku”) and Kaken Pharmaceutical Co. Ltd. (Tokyo, Japan; “Kaken”) announced today that HERNICORE® 1.25 units for intradiscal injection (generic name: condoliase) has been listed in the National Health Insurance drug price list. The planned launch date is August 2018.

HERNICORE® 1.25 units for intradiscal injection ("the Agent") is a new treatment option for lumbar disc herniation whose active pharmaceutical ingredient is condoliase. This is the first therapeutic Agent in Japan with intradiscal administration. It does not require a general anesthesia and is less invasive to the patient than surgical treatment. Seikagaku obtained New Drug Application (“NDA”) approval for the Agent in Japan on March 23, 2018, and Kaken will distribute it in Japan. As improvement effects to the symptoms of lumbar disc herniation by prolapse of the posterior longitudinal ligament* are expected by a single administration of the Agent, Seikagaku and Kaken believe that this new treatment option is able to contribute to quality of life of patients.

The Agent is a pharmaceutical with a novel mechanism of action, and from the standpoint of safety assurance, the special Warnings and Precautions for Use in the package insert reads, “This Agent should be administered under the supervision of a physician with sufficient knowledge and experience in the diagnosis and treatment of lumbar disc herniation. It should be administered by a physician with proficiency in performing lumbar puncture.”

Accordingly, at this time specific physician requirements and facilities requirements are being considered. Kaken will commence sales of the Agent after these requirements have been determined and strive for a phased rollout while promoting appropriate use.

*Herniation by prolapse of the posterior longitudinal ligament: a type of herniation and its structure is that it is covered by the posterior longitudinal ligament, although the hernia extends beyond the outermost layer of the annulus fibrosus

<Overview of the Agent>
Product name: HERNICORE® 1.25 Units for Intradiscal Injection

Generic name: condoliase

Efficacy and effects: Lumbar disc herniation by prolapse of the posterior longitudinal ligament for which sufficient improvement cannot be obtained through conservative treatment Usage and dosage: For adults, 1.25 units of condoliase are administered by a single injection in the intervertebral disc that is the source of the symptoms.

NHI drug price: 81,676 yen (1 bottle containing 1.25 units)

New Drug Application approval date: March 23, 2018

Date of listing in the National Health Insurance drug price list: May 22, 2018

Launch date: August 2018 (planned)

Marketing authorization holder: Seikagaku Corporation

Distributor: Kaken Pharmaceutical Co. Ltd.

Mechanism of action: It is expected that condoliase degrades chondroitin sulfate, chondroitin, and hyaluronic acid and also improves the clinical manifestations of herniation by lowering the internal pressure of the intervertebral disc due to dissolving the glycosaminoglycans* within the nucleus pulposus of the intervertebral disc, and lowering the water-holding capacity of the nucleus pulposus.

* Glycosaminoglycans (GAG): A major component of complex carbohydrates. Chondroitin sulfate and hyaluronic acid etc.

<Regarding lumbar disc herniation and therapies>
Lumbar disc herniation is the partial protrusion of the nucleus pulposus at the core of each intervertebral disc or the annulus fibrosus, the disc's outer layer. The resulting pressure on the spinal nerve root causes pain and numbness.

Current treatments are generally categorized into conservative treatments for temporal pain relief (rest and pharmaceutical methods such as NSAIDs) and surgical treatments. As this Agent specifically degrades GAGs in the nucleus pulposus, resulting in decrease in the pressure on the nerve root, it is positioned as an innovative treatment of lumbar disc herniation.

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