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SEIKAGAKU CORPORATION
Kaken Pharmaceutical Co., Ltd.

Seikagaku and Kaken Announce the Launch 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 Kaken will launch HERNICORE® 1.25 units for intradiscal injection (generic name: condoliase, "the Agent") on August 1, 2018. Seikagaku obtained New Drug Application (“NDA”) approval for the Agent in Japan on March 23, 2018.

The Agent contains condoliase as an active pharmaceutical ingredient and is expected to provide a new treatment option for the patients with lumbar disc herniation. This is the first approved drug in Japan to be treated via intradiscal administration. It does not require a general anesthesia and is far less invasive to the patient than surgical treatment. As a single administration of the Agent expects to improve the symptoms of lumbar disc herniation by prolapse of the posterior longitudinal ligament*, Seikagaku and Kaken believe that this new treatment option is able to contribute to quality of life of patients.

*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

The Agent is the first drug to be classified as intradiscal enzyme injection therapy in Japan. Therefore, physician requirements have been established for the use of the Agent. This is to promote appropriate use and ensure safety. The Agent can be used if the requirements of a supervisory physician of the Japanese Society for Spine Surgery and Related Research or the Neurospinal Society of Japan, a physician under such supervision, or a physician who participated in the clinical trial of the Agent are satisfied during the initial launch period. The Japanese Society for Spine Surgery and Related Research has published the details of the requirements on its website (http://www.jssr.gr.jp/) so that the Agent can be used appropriately. (The physician requirements are also under review at the Neurospinal Society of Japan.)

In regards to the physician requirements, Seikagaku and Kaken will carefully examine the safety information about six months to a year after we start selling the Agent. We will proceed with the review upon agreement with the Pharmaceuticals and Medical Devices Agency in cooperation with the relevant societies.

Seikagaku and Kaken will continue to provide information and make efforts to gradually expand the use of the Agent while paying attention to promoting its appropriate use and ensuring safety.

<Photograph of the HERNICORE® 1.25 Units for Intradiscal Injection>

<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 1, 2018
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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