



May 19, 2021

## Ono and Seikagaku Announce the Launch of JOYCLU<sup>®</sup> 30mg Intra-articular Injection, a Joint Function Improvement Agent, in Japan

Ono Pharmaceutical Co., Ltd. (Osaka, Japan; President and Representative Director: Gyo Sagara; "Ono") and Seikagaku Corporation (Tokyo, Japan; President and CEO: Ken Mizutani; "Seikagaku") announced today that Ono has launched JOYCLU<sup>®</sup> 30mg Intra-articular Injection (generic name: diclofenac etalhyaluronate sodium; "JOYCLU"), a joint function improvement agent, for which Seikagaku received the manufacturing and marketing approval in Japan in March 2021.

JOYCLU is a formulation in which hyaluronic acid and diclofenac (an anti-inflammatory drug) are chemically bound using Seikagaku's own proprietary technology. It is designed to release diclofenac by hydrolysis in the joint. JOYCLU is approved for the treatment of osteoarthritis (knee joint and hip joint) and expected to improve the symptoms of osteoarthritis by the intra-articular injection once every four weeks. Further, since JOYCLU is administered directly into the joint cavity as an injection, systemic exposure to diclofenac is low, and the risk of systemic adverse drug reaction is considered to be low.

JOYCLU is the first ethical drug having the indication of osteoarthritis of the hip joint in Japan among the joint function improvement agents.

Ono and Seikagaku aim to contribute to the improvement of quality of life (QOL) in patients by providing a new treatment option for osteoarthritis (knee joint and hip joint).

Product name	JOYCLU <sup>®</sup> 30mg Intra-articular Injection	
Generic name	diclofenac etalhyaluronate sodium	
Indication	Osteoarthritis (knee joint and hip joint)	
Dosage and administration	The usual adult dosage is 1 syringe per dose (30 mg of diclofenac etalhyaluronate sodium) injected intra-articularly every 4 weeks.	
Date of manufacturing and marketing approval	March 23,2021	
NHI price listing date	May 19, 2021	
NHI drug price	¥4,394 (30mg/3mL syringe)	
Manufacturing and marketing authorization holder	Seikagaku Corporation	
Distributor	Ono Pharmaceutical Co., Ltd.	

## Overview of JOYCLU

## Product photograph

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## About Osteoarthritis

Osteoarthritis is a disease caused by articular cartilage damage, leading to inflammation and pain, which results in deterioration of QOL. Osteoarthritis of the knee is caused by factors such as aging, and osteoarthritis of the hip is caused by congenital and other factors. The number of symptomatic patients with knee osteoarthritis in Japan is estimated to be about 7.8 million. The disease is particularly common in women and is reported to affect approximately 70% of women in their 70s.<sup>\*1</sup> Also, based on X-ray diagnosis, the prevalence rate of osteoarthritis of the hip is reported to be in the range of 1.0 - 4.3% of the population, 0.0 - 2.0% in men and 2.0 - 7.5% in women.<sup>\*2</sup>

- \*1: Yoshimura N et al., J Bone Miner Metab, 2009;27:620-8
- \*2: *Clinical Practice Guideline on the Management of Osteoarthritis of the Hip* (2016). 2nd Edition. Tokyo: Nankodo Co., Ltd.; 2016: 10-13.

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