



FOR IMMEDIATE RELEASE

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Eisai Co., Ltd.
SEIKAGAKU CORPORATION

Eisai and Seikagaku Enter into Agreement for the Co-development and Marketing Alliance of SI-613, a Treatment of Osteoarthritis, in China

Eisai Co., Ltd. (Headquarters: Tokyo, CEO: Haruo Naito, “Eisai”) and Seikagaku Corporation (Headquarters: Tokyo, President: Ken Mizutani, “Seikagaku”) announced today that the companies have entered into an agreement for the co-development and marketing alliance in China for SI-613 (diclofenac conjugated sodium hyaluronate), a therapeutic agent for osteoarthritis discovered by Seikagaku.

On the basis of this agreement, the companies will jointly develop SI-613 in China for a treatment of knee osteoarthritis. After obtaining approval, Seikagaku will supply products to Eisai, and Eisai will be responsible for distribution. The companies will cover an equal share of the development cost, and Eisai will pay Seikagaku the upfront payment, and development as well as sales milestones.

Osteoarthritis is a disease caused by the articular cartilage damage due to aging and other factors, leading to inflammation and pain, which result in impaired quality of life (QOL). Knee osteoarthritis is one of the most frequent cases among thereof, and the number of symptomatic patients with knee osteoarthritis in China is estimated to be approximately 47 million*¹, and it is anticipated that the number will continue to increase as the population ages.

SI-613 is diclofenac conjugated sodium hyaluronate created by Seikagaku using their proprietary drug-binding technology to chemically bond hyaluronic acid and diclofenac (an anti-inflammatory drug). This material has the analgesic and anti-inflammatory effects of diclofenac, which is designed to be sustained-released*² by a drug delivery system*³, in addition to the joint function improving effect of sodium hyaluronate. Hence, it is expected that SI-613 rapidly and continuously reduces the pain and inflammation associated with osteoarthritis.

Under this agreement, Eisai aims to contribute to patients with knee osteoarthritis that is unmet medical needs by utilizing the knowledge and networks that Eisai has cultivated through its China business. Seikagaku will seek to maximize the value of SI-613 in China by leveraging Eisai’s business base in China.

Through the development and commercialization of SI-613, the companies will provide new treatment options in China for knee osteoarthritis and contribute to improving the QOL of patients.

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<Notes to editors>

1. About Eisai Co., Ltd.

Eisai Co., Ltd. defines our corporate mission as "giving first thought to patients and their families and to increasing the benefits health care provides," which we call our *human health care (hhc)* philosophy. With approximately 10,000 employees working across our global network of R&D facilities, manufacturing sites and marketing subsidiaries, we strive to realize our *hhc* philosophy by delivering innovative products to address unmet medical needs, with a particular focus in our strategic areas of Neurology and Oncology. As a global pharmaceutical company, our mission extends to patients around the world through working with key stakeholders to improve access to medicines in developing and emerging countries.

For further information on Eisai Co., Ltd., please visit <https://www.eisai.com>.

2. About Seikagaku Corporation

Seikagaku Corporation is an R&D-oriented pharmaceutical company that focuses on glycoscience as an area of specialization. Since its foundation in 1947, Seikagaku has continuously focused on the possibilities of glycoscience and developed original, beneficial pharmaceutical products and medical devices in the fields of orthopedic disorders and ophthalmic diseases. Under a unique business model of specializing in R&D and manufacturing without having an in-house pharmaceuticals sales division, Seikagaku contributes to healthy and fulfilling lives for people around the world by marketing products globally in collaboration with companies having strengths in particular countries and product areas.

For further information on Seikagaku Corporation, please visit <https://www.seikagaku.co.jp/en/>

3. About SI-613

SI-613 is diclofenac conjugated sodium hyaluronate created by Seikagaku using their proprietary drug-binding technology to chemically bond hyaluronic acid and diclofenac (an anti-inflammatory drug). This material has the analgesic and anti-inflammatory effects of diclofenac, which is designed to be sustained-released*² by a drug delivery system*³, in addition to the joint function improving effects of sodium hyaluronate. It is expected that SI-613 rapidly and continuously reduces the pain and inflammation associated with osteoarthritis (such as knee joint). Also, since this is administered directly into the joint cavity by injection, it is considered that the amount of diclofenac systemic exposure and the risk of eliciting systemic adverse drug reaction are to be low.

In Japan, Seikagaku submitted a new drug application ("NDA") for manufacturing and marketing approval for SI-613 on January 6, 2020.

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References:

*1: For the estimated data regarding the number of patients with knee osteoarthritis

- Data of morbidity prevalence rate - The Prevalence of Symptomatic Knee Osteoarthritis in China, ARTHRITIS & RHEUMATOLOGY(2016)
- Estimated data calculated from United Nations World Population Estimates - World Population Prospects, URL : <http://www.un.org/en/development/desa/population/>

*2: Sustained release is a gradual release of the active pharmaceutical ingredients of a drug to achieve a sustained therapeutic effect.

*3: Drug delivery system (DDS) is a technology for the controlled release, targeting, and absorption improvement of drugs.