

May 23, 2023

MITSUBISHI GAS CHEMICAL COMPANY, INC.

**MGC Commences a Phase I Clinical Trial  
of Denosumab Biosimilar SPD8 in Japan**

Mitsubishi Gas Chemical Company, Inc. (MGC; Head Office: Chiyoda-ku, Tokyo; President: Masashi Fujii), in collaboration with GlycoNex, is pleased to announce that their Denosumab biosimilar, SPD8, developed for the treatment of osteoporosis, has received regulatory approval from the Pharmaceuticals and Medical Devices Agency (PMDA) in Japan to initiate a Phase I clinical trial. The first patient was enrolled, marking a significant milestone in the development of SPD8. The trial will be conducted at clinical research centers in Tokyo and Osaka, with a planned enrollment of postmenopausal healthy women, who will undergo pharmacokinetic and safety assessments in a double-blind design compared to the reference product.

Denosumab, known for its ability to inhibit osteoclasts and slow down bone loss, has already been developed for osteoporosis and the treatment of bone metastases in cancer. Both products are included in MGC and GlycoNex's biosimilar program, which aims to provide highly similar medications in terms of composition, quality and safety to the reference products. Biosimilars are affordable alternatives to reference products, offering more treatment options accessible to a larger patient population. SPD8, a biosimilar jointly developed by MGC and GlycoNex, exhibits highly similar quality attributes to the reference product and will be manufactured in Japan for supply to the Japanese market.

The elderly, especially women, are at a high risk of developing osteoporosis. As individuals age, particularly after menopause and postmenopausal, there is a significant decline in hormone levels in the body. Hormones play a crucial role in maintaining bone density and skeletal health, and the reduction in hormones lead to a decrease in bone density and an increased risk of fractures.

The global sales of two Denosumab-containing drugs amounted to \$3.6 billion and \$2 billion respectively in 2022. With the increasing elderly population and growing awareness of osteoporosis risks, the market for Denosumab continues to expand. In addition to the Japanese market, MGC and GlycoNex are actively pursuing global development plans, aiming to provide hope and assistance to patients with osteoporosis worldwide. SPD8 is expected to fulfill the needs of patients suffering from osteoporosis.

&lt;Reference&gt;

Successful Mass-culture of Cells Producing Denosumab Biosimilar candidate (March 07, 2019)

<https://www.mgc.co.jp/eng/corporate/news/2019/successful-mass-culture-of-cells-producing-denosumab-biosimilar-candidate.html>

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**INQUIRIES**

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