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Chugai Launches Enspryng (Satralizumab) Subcutaneous Injection 120 mg Syringe, the pH-Dependent Binding Humanized anti-IL-6 Receptor Monoclonal Antibody

- Subcutaneous injection for the treatment of neuromyelitis optica spectrum disorder (NMOSD) in both adults and children
- Enspryng, the first approved drug applying Chugai's proprietary recycling antibody technology, may provide convenience for people by subcutaneous injection every four weeks

TOKYO, August 26, 2020 -- [Chugai Pharmaceutical Co., Ltd.](#) (TOKYO: 4519) announced the launch of Enspryng® Subcutaneous Injection 120 mg Syringe [generic name: satralizumab (genetical recombination)] (hereafter, Enspryng) for the prevention of relapses of neuromyelitis optica spectrum disorder (NMOSD) [including neuromyelitis optica (NMO)]. Enspryng is the pH-dependent binding humanized anti-IL-6 receptor monoclonal antibody created by Chugai. In Japan, the product received manufacturing and marketing approval on June 29, 2020, and was listed on the National Health Insurance (NHI) reimbursement price list today.

“We are very pleased that Enspryng, which is the first approved drug applying our proprietary recycling antibody technology, is now available as a treatment for NMOSD with a novel mechanism of action in Japan,” said Chugai’s President and COO, Dr. Osamu Okuda. “As the first subcutaneous treatment for NMOSD administered every four weeks, we are confident that Enspryng will contribute to the treatment of a wide range of people from adults to children both in terms of relapse prevention and convenience.”

Enspryng, created by Chugai, is the pH-dependent binding humanized anti-IL-6 receptor antibody, which was the first product developed by applying our proprietary recycling antibody technology. The drug is believed to prevent relapse of NMOSD by inhibiting the cytokine IL-6 which is a key driver in NMOSD. In two global phase III clinical studies in NMO and NMOSD patients, the primary endpoint was achieved with satralizumab either as an add-on therapy to baseline immunosuppressant treatment (NCT02028884) or as monotherapy (NCT02073279). These studies represent one of the largest clinical trial programs undertaken for this rare disease. Enspryng has been approved in Japan, the U.S. Canada, and Switzerland. Enspryng is designated as an orphan drug in Europe. The application was accepted for review by the European Medicines Agency in 2019.

As a leading company in biopharmaceuticals, Chugai will continue to create pharmaceutical products that meet unmet medical needs through the development of innovative technologies and their application, contributing to healthcare and the health of people around the world.

Drug Information

Product name: Enspryng® Subcutaneous Injection 120 mg Syringe

Nonproprietary name: Satralizumab (genetical recombination)

Indications: Prevention of relapses of NMOSD (including NMO)
[Precautions concerning indications]

- Enspryng should be used in patients with NMOSD (including NMO)*
* Should be referred to the “Guidelines for the Management of Multiple Sclerosis and Neuromyelitis Optica, 2017” (Japanese Society of Neurology) .
- The data showing efficacy for anti-AQP4 antibody-negative patients are limited. Enspryng should be administered to anti-AQP4 antibody-positive patients.

Dosage and administration:

The usual dosage for adults and children is a single dose of 120 mg satralizumab (genetical recombination) administered by subcutaneous injection at weeks 0, 2, and 4, and then once every 4 weeks thereafter.

[Precautions concerning dosage and administration]

- If a scheduled dose is missed, administer ENSPRYNG as soon as possible and then according to the original dosing interval from that point onward.
- After a certain period of administration of satralizumab, the frequency of relapse should be investigated. If it is considered that the benefit of satralizumab is not expected (e.g. the frequency of relapse is not decreased), discontinuation of satralizumab administration should be considered.
- In pediatric patients, consideration should be given to the weight of the patient enrolled in the clinical study to determine whether the drug could be administered.

Date of approval: June 29, 2020

Date of NHI reimbursement price listing: August 26, 2020

Date of launch: August 26, 2020

Shelf life: 24 months

Drug price: Enspryng® Subcutaneous Injection 120 mg Syringe, JPY 1,532,660/Syringe

<Reference>

•SAkuraSky study

Results from Phase III SAKuraSky Study for Chugai’s Enspryng in Neuromyelitis Optica Spectrum Disorder
Published in The New England Journal of Medicine Online (November 29, 2019)

https://www.chugai-pharm.co.jp/english/news/detail/20191129110000_644.html

•SakuraStar study

Positive Results from the Second Phase III SAKuraStar Study for Chugai's Enspryng in Neuromyelitis Optica Spectrum Disorder (NMOSD) Published in The Lancet Neurology (April 24, 2020)

https://www.chugai-pharm.co.jp/english/news/detail/20200424150001_714.html

About neuromyelitis optica spectrum disorder (NMOSD)¹

NMOSD is an autoimmune disease of the central nervous system characterized by inflammatory lesions in the optic nerves and spinal cord, and cause continual and significant decrease in quality of life due to permanent neurological disability. Patients with NMOSD frequently experience a relapsing disease course with repeated attacks leading to accumulating neurological damage and disability. Symptoms may include visual impairment, motor disability, pain leading to decreased quality of life. In some cases, attacks of NMOSD result in death. Aquaporin-4 antibodies (AQP4-IgG), pathogenic antibodies, are detected in around 70-80% of NMOSD people. AQP4-IgG is known to target and damage a specific central nervous cell type called astrocytes, resulting in inflammatory demyelinating lesions of the optic nerve(s), spinal cord and brain²⁻⁵. The inflammatory cytokine IL-6 is now emerging as an important factor in NMOSD pathogenesis⁶⁻¹⁰.

Diagnostic criteria introduced in 2006 for NMO were characterized by inflammation of the optic nerve (optic neuritis) and the spinal cord (myelitis). These were revised in 2007 with the definition of NMOSD, proposed for diseases with either optic neuritis or myelitis. In 2015, the definition of NMOSD further revised to include a broader spectrum of diseases. The diagnostic term NMOSD is now accepted¹¹.

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Sources

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