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Chugai's Enspryng receives FDA approval for NMOSD

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An alternative treatment with a novel mode of action for the anti-aquaporin-4 antibody seropositive neuromyelitis optica spectrum disorder approved in the United States.

Tokyo based Chugai Pharmaceutical Co. Ltd., announced that the United States Food and Drug Administration (FDA) has approved the anti-humanized IL-6 receptor monoclonal antibody with PH-dependent binding, Enspryng ™ (generic name: satralizumab) (here: enspryng) created by Chugai for the treatment of adults with neuromyelitis optic spectrum disorder (NMOSD) positive for anti-aquaporin-4 (AQP4) antibodies.

Enspryng is administered subcutaneously every four weeks. Enspryng was granted the Innovative Treatment designation in December 2018 and the US Biologics License Application (BLA) was filed in August 2019 by Genentech Inc., a member of the Roche Group.

This approval is based on the results of two global Phase III clinical studies in people with NMOSD: the SAkuraSky study (NCT02028884) and the SAkuraStar study (NCT02073279). SAkuraSky is a study that evaluates Enspryng in combination with standard immunosuppressive therapy, and SAkuraStar is a study that evaluates enspryng as monotherapy.

Enspryng, created by Chugai, is a humanized anti-IL-6 receptor antibody exhibiting PH-dependent binding, which was the first product developed by applying our proprietary recycling antibody technology. The drug is believed to prevent relapse of NMOSD by inhibiting IL-6 signal signaling which is a key factor in NMOSD. Enspryng has been approved in Canada, Japan and Switzerland. Enspryng is designated as an orphan drug in Europe. The request was accepted for review by the European Medicines Agency in 2019.