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EMA and FDA accept marketing applications for Chugai's Satralizumab

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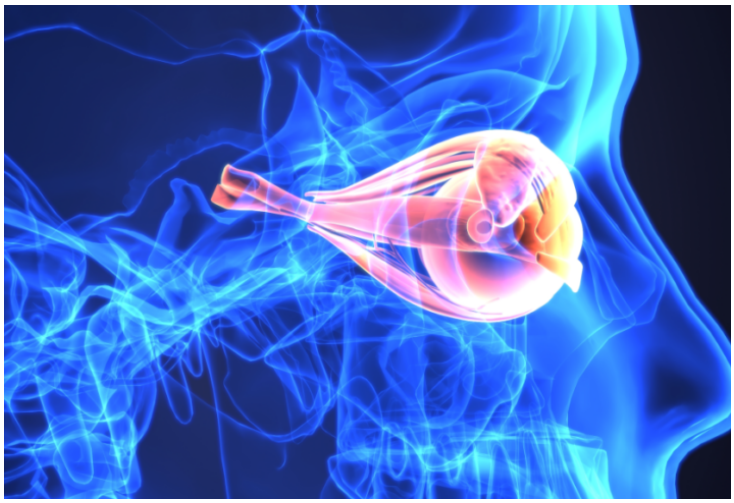
The applications will be reviewed under Accelerated Assessment by EMA



Chugai Pharmaceutical has announced that the European Medicines Agency (EMA) has accepted the Marketing Authorization Application for satralizumab, an anti-interleukin-6 (IL-6) receptor humanized recycling antibody, for the treatment of adult and adolescent patients with neuromyelitis optica spectrum disorder (NMOSD).

EMA has granted Accelerated Assessment status for satralizumab. The USFDA has also accepted the Biologics License Application (BLA) for satralizumab. The EMA's Committee for Medicinal Products for Human Use (CHMP) recommendation and the FDA decision are expected in 2020.

Dr. Yasushi Ito, Chugai's Executive Vice President, Co-Head of Project & Lifecycle Management Unit said, "NMOSD is a disease with high unmet medical needs, which causes visual impairment and motor disability in the course of disease progression. Satralizumab is the investigational medicine that has demonstrated a clinically meaningful treatment effect as both monotherapy and add-on therapy to baseline treatment. We are collaborating with Roche and regulators to deliver this new treatment option to patients as soon as possible."

Accelerated Assessment reduces the timeframe for the EMA and CHMP to review the marketing authorization, signifying the treatment is of major interest for public health and therapeutic innovation. These applications are based on the results from global phase III clinical studies in patients with NMOSD.