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Roche Group

Launch of Subcutaneous Injection formulation, Actemra®, for a Treatment of Rheumatoid Arthritis The First Anti-IL-6 Receptor Antibody in Subcutaneous market

May 24, 2013 - Chugai Pharmaceutical Co., Ltd. [Main Office: Chuo-ku, Tokyo. Chairman & CEO: Osamu Nagayama] (hereafter, "Chugai")] announced today that it launched the subcutaneous injection formulation of the humanized anti-human interleukin-6 (IL-6) receptor monoclonal antibody (tocilizumab; genetical recombination), "Actemra®162mg Syringe for SC Injection and Actemra®162mg Auto-Injector for SC Injection", as the indication of "rheumatoid arthritis that does not respond sufficiently to one or more existing therapies (including inhibition of structural joint damage)." on May 24, 2013. Actemra® received a manufacturing and marketing approval on March 25, 2013 and was listed on the National Health Insurance (NHI) reimbursement price list on May 24, 2013.

Actemra® is the first antibody drug (humanized monoclonal antibody) originating from Japan produced by utilizing genetic recombinant technology based on a monoclonal antibody against the anti-IL6 receptor created in collaboration between Chugai and Osaka University. It works by inhibiting biological activity of IL-6 through competitively blocking the binding of IL-6 to its receptor.

"Actemra®162mg Syringe for SC Injection and Actemra®162mg Auto-Injector for SC Injection" are the first anti IL-6 receptor treatment in the subcutaneous injection formulation market. This new subcutaneous formulation of Actemra®, in addition to the already launched intravenous infusion, will offer treatment options that suit patients' life style or meet the needs of health care providers, contributing to improved convenience of Actemra® therapy. Subcutaneous formulation requires short time of administration and will reduce the burden on patients of visits to medical institutions as it can be administrated at home by self-injection. For health care providers, it has additional benefit as it does not require preparation procedures prior to injection.
Moreover, Actemra®162mg Auto-Injector is the first auto-injection device for rheumatoid arthritis treatment in Japan that enables users to inject with single pushbutton. It is expected to reduce patients' burden and will decrease the risk of infection with its design that prevents patients' needle-stick accidents after injection.

The subcutaneous formulation was submitted in the US and Europe in December 2012.

Chugai focuses on bone and joint diseases area as one of the strategic domains, and believes that it can contribute to the treatment of bone and joint diseases by providing new therapeutic options to patients and medical professionals.

[Reference information]

Brand name: Actemra® 162mg Syringe for SC Injection
Actemra® 162mg Auto-Injector for SC Injection

Japan accepted name (JAN): tocilizumab (genetical recombination)

Indications: Rheumatoid arthritis that does not respond sufficiently to existing therapies (including inhibition of structural joint damage)

Dosage and administration: The recommended dose of tocilizumab (genetical recombination) for adults is 162 mg as a single subcutaneous injection administered at 2-week intervals.

Date of approval: March 25, 2013

Date of listing in the NHI reimbursement price: May 24, 2013

Date of launch: May 24, 2013

Shelf life: 2 years

NHI price: Actemra® for SC Injection 162mg Syringe / 38,056 yen
Actemra® for SC Injection 162mg Auto-Injector / 38,200 yen