This English version is intended to be a reference material for the convenience of users. In the event of inconsistency between the Japanese original and this English translation, the former shall prevail.

Summary of Investigation Results

Tocilizumab (genetical recombination)

September 24, 2019

Non-proprietary name

Tocilizumab（genetical recombination）

Branded name (Marketing authorization holder)

a. Actemra for Intravenous Infusion 80 mg, 200 mg, 400 mg (Chugai Pharmaceutical Co., Ltd.)

b. Actemra Syringe for Subcutaneous Injection 162mg, Auto-Injector for Subcutaneous Injection 162mg (Chugai Pharmaceutical Co., Ltd.)

Indications

a.

- The following diseases in patients who have had an inadequate response to existing treatments:
  Rheumatoid arthritis (including the inhibition of progression of structural joint damage), polyarticular-course juvenile idiopathic arthritis, systemic juvenile idiopathic arthritis, adult Still's disease
- Improvement of various symptoms and laboratory findings limited to patients for whom lymph node resection is not indicated (increased C-reactive protein, increased fibrinogen, increased erythrocyte sedimentation rate, decreased haemoglobin, decreased albumin, generalized fatigue) associated with Castleman’s disease
- Cytokine release syndrome associated with tumor-specific T-cell infiltration therapy

b.

- The following diseases in patients who have had an inadequate response to existing treatments:

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Rheumatoid arthritis (including the inhibition of progression of structural joint damage), Takayasu's arteritis or giant cell arteritis

Summary of revisions

"Hepatic impairment" should be added to the Clinically Significant Adverse Reactions section.

Investigation results and background of the revision

Cases of hepatic impairment have been reported in patients treated with tocilizumab in Japan and overseas. MHLW/PMDA concluded that revision of the package insert was necessary based on the results of their investigation of the currently available evidence and in consultation with expert advisors.

Number of cases and patient mortalities reported in Japan during the previous 3 fiscal years

A total of 11 cases* involving hepatic impairment have been reported to date (A causal relationship between the drug and event could not be established in any of these cases.)
No patient mortalities have been reported to date.
*Cases complicated with hepatitis B are excluded.