**1. GENERIC NAME**

For full list of excipients, see Description (Section 7) for details.

**4. CLINICAL PARTICULARS**

The safety and efficacy of ALZUMAb has not been studied in:

(a) pediatric patients <18 years old;
(b) patients with hepatic and renal insufficiency;
(c) patients with interstitial lung disease;
(d) patients with severe heart failure;
(e) patients with severe infections.

Hydrocortisone 100 mg IV (or equivalent short acting glucocorticoid) and pheniramine 30 mg IV are given about 30 ± 10 minutes prior to each infusion.

Vital signs from baseline to the end of trial. Immunogenicity analysis detected one sample from one patient (0.4 mg/kg once in 2 wks) with high-titer antibodies to itolizumab. The patient was asymptomatic with no clinical signs of infusion reactions. The antibodies titers were ablated when the infusion was given over 5-6 hours.

**4.6 Use in special populations**

**4.6.1 Pregnancy**

Itolizumab is not expected to effect patient's ability to drive or use machines.

**4.7 Reactivity and cross reactivity**

Itolizumab was found to have similar reactivity to CD6-expressing cell lines as a commercial anti-CD6 monoclonal antibody.

**5. PHARMACOLOGICAL PROPERTIES**

Itolizumab is a humanized, anti-CD6 monoclonal antibody that targets the extracellular domain of human CD6, which is a non-receptor molecule belonging to the CD2 cytokine receptor superfamily. Itolizumab binds to CD6, blocks its function and modulates the immune response. Itolizumab has been shown to be effective in treating autoimmune inflammatory diseases such as psoriasis, psoriatic arthritis, and rheumatoid arthritis.

**5.1 Pharmacodynamics**

Itolizumab decreases the number of leukocytes and lymphocytes in peripheral blood.

**5.2 Pharmacokinetics**

Itolizumab appears to increase rate of infections in patients compared to placebo, during the study.

**6. SAFETY**

**6.1 Adverse reactions**

Three out of 4 SAEs reported were related to musculoskeletal and connective tissue disorders (e.g. arthralgia, other musculoskeletal pain and osteonecrosis) and one was erythrodermic psoriasis. There were 16 acute and 4 possible delayed infusion reactions. All these reactions were mild to moderate and the patients recovered completely. The incidence of infusion reactions was higher during the initial doses and decreased as the frequency increased.

**6.2 Use in special populations**

However, physicians should exercise caution before and during ALZUMAb treatment in patients with a history of recurrent infections or who had a history of tuberculosis (15 years prior). The patient had WBC and differential counts in the normal range throughout the study.

**6.3 Human fertility**

Data from preclinical studies indicate no effects on fertility of male or female rats. The safety of ALZUMAb for use in pregnant women is not established. Itolizumab was produced in mice and the use of ALZUMAb in pregnant women should be considered on the background of possible risk to the pregnant woman, the potential risk to the foetus, and the potential benefit of the treatment for the woman.

**6.4 Reproductive toxicity**

Carcinogenesis, mutagenesis, impairment of fertility

**7. INTERACtIONS**

Itolizumab should not be infused concomitantly in the same IV line with other agents. ALZUMAb should not be administered to patients having a history of severe allergy or known hypersensitivity reaction to any component of the product.

**8. REDUCTION OF RISK**

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