**Pre-clinical Toxicology Summary of Ilizomab**

**Introduction**

This summary provides an overview of the preclinical toxicology evaluation of Ilizomab, a monoclonal antibody targeting [specific immune pathway], conducted in rodent and non-human primate models to assess its safety, pharmacokinetics, and potential toxicity profile.

**Study Design**

* **Species:** Rats and Cynomolgus monkeys
* **Duration:** 28-day and 90-day repeat-dose studies
* **Doses:** Low (1 mg/kg), Medium (5 mg/kg), High (15 mg/kg)
* **Endpoints Assessed:**
  + Clinical observations (body weight, food consumption, clinical signs)
  + Hematology, serum chemistry, and cytokine profiling
  + Organ pathology (gross and histopathology)

**Key Findings**

* **General Tolerability:**
  + Ilizomab was well tolerated at doses up to **15 mg/kg** in both species
  + No treatment-related mortality observed
* **Hematological Effects:**
  + Mild, dose-dependent decreases in lymphocyte counts at high doses, reversible after treatment cessation
* **Liver and Renal Toxicity:**
  + No significant liver enzyme elevations or renal dysfunction markers detected
* **Cytokine Modulation:**
  + Dose-dependent reduction in inflammatory cytokines (IL-6, TNF-α), consistent with proposed mechanism of action
* **Immunogenicity:**
  + Low anti-drug antibody formation in non-human primates
* **Observed Side Effects:**
  + Mild to moderate **fatigue** was noted in some animals, resolving post-dosing
  + **Nausea** observed at higher doses but did not impact overall health outcomes
  + **Syncope-like episodes** recorded in isolated cases at **15 mg/kg**, transient and not dose-limiting

**Conclusion**

Ilizomab demonstrated a favorable safety profile in preclinical models, with no dose-limiting toxicities identified. Mild fatigue, nausea, and rare instances of syncope were observed but were not associated with long-term adverse effects. The findings support further clinical development in SLE patients, with careful monitoring of hematological parameters and potential side effects during clinical trials.