**Objectives:**

**Primary Objective:** To determine the effectiveness of XmAb5871 to maintain SLE disease activity suppression achieved by a brief course of XmAb5871 treatment in SLE patients.

**Secondary Objectives:**

- To evaluate time to loss of SLE disease activity suppression
- To assess a brief course of XmAb5871 treatment in SLE patients
- To evaluate the safety of XmAb5871 in the short term
- To evaluate the pharmacokinetics of XmAb5871

**Exploratory Objectives:**

- To determine the effects of XmAb5871 on adhesion molecules
- To evaluate the safety of XmAb5871 in the long term
- To evaluate the pharmacodynamics of XmAb5871

**Patient Population:** Male and female patients aged 18 to 75 inclusive with active SLE on background immunosuppressive therapy. A brief course of XmAb5871 treatment is administered to patients.

**Study Design:** A double-blind, placebo-controlled study of 107 patients with SLE. Patients were randomized to receive either XmAb5871 or placebo. The primary endpoint was time to loss of improvement in SLE disease activity.

**Safety:**

- **TEAEs:** Total 107 patients were reported in 61 patients. Of these, 41 patients were considered serious and 6 patients were discontinued. No SLE-related mortality was observed. The most common adverse events (AEs) in all patients were shown below.

**Primary Endpoint:**

- **Time to Loss of Improvement Thru Day 225 Planned Visit – Efficacy Evaluable:** The primary endpoint was time to loss of SLE disease activity suppression at Day 225. The efficacy population was all evaluable patients (N=52). The first secondary endpoint was time to loss of improvement in SLE disease activity status (N=52).

**Secondary Endpoints:**

- **Time to Loss of Improvement Thru Day 225 Planned Visit – Intent to Treat:**

**Conclusions:**

- Positive trend in primary endpoint, proportion of efficacy-evaluable patients who did not experience loss of improvement (LOI) by Day 225, but did not meet statistical significance.
- 18% (10/57) of patients discontinued early for toxicity.
- Median time to LOI (in secondary population) was 170 days.
- XmAb5871-treated patients remained without increase in disease activity and on study longer than the placebo patients.
- A 6% increase in SLE disease activity was reduced by 47% for patients treated with XmAb5871 (median 203 vs. 133 days for patients on placebo, hazard ratio = 0.53, 95% CI 0.32-0.90).
- XmAb5871-treated patients showed a trend of greater improvement in SLE disease activity status compared to the placebo group.
- XmAb5871 showed no significant difference in safety profile compared to previous studies.

**Authors:**


**Keywords:** SLE, Placebo-controlled study, immunosuppressants, SLEDAI, safety, pharmacokinetics, adverse event

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**Table 1:**

<table>
<thead>
<tr>
<th>Endpoint</th>
<th>XmAb5871 (N=52)</th>
<th>Placebo (N=52)</th>
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<tbody>
<tr>
<td>Time to LOI</td>
<td>170 (20-252)</td>
<td>133 (34-225)</td>
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</tbody>
</table>

**Conclusion:**

- The primary endpoint was time to loss of improvement at Day 225. The efficacy population was all evaluable patients (N=52). However, the first secondary endpoint was time to loss of improvement was significant (p = 0.03).