INTRODUCTION

Lupus erythematosus (LE) is an autoimmune-mediated disorder involving glomerulonephritis and vasculitis in combination with autoantibodies against DNA, RNA, and histones, as well as complement consumption.

Complete complement consumption (3P) in LE is accompanied by the glomerular lesion (3G), which is characterized by vascular injury and glomerular deposits. Patients with LE are at risk of life-threatening complications such as renal failure, cardiovascular disease, and pulmonary hypertension.

In this interim analysis, ANX009 administered subcutaneously was well tolerated and demonstrated a favorable safety profile in 5 patients with active lupus nephritis.

METHODS

- **Patients**: Patients ≥18 and ≤75 years old meeting the following criteria will be included:
  - Evidence of classical complement activation at screening
  - Lupus nephritis (LN) with C4/C3 ratio (screening to day 1) ≤0.4
  - Positive anti-dsDNA (negative: <25 IU), IU/mL
  - UPCR D1 predose, g/g
  - Class III or IV LN

- **Treatment**: ANX009 is a subcutaneously administered antigen that targets complement C1q.

- **Endpoints**: Key endpoints include renal response, proteinuria, and SERBAMH.

RESULTS

- **Intervention**: ANX009 was administered at a dose of 0.5 mg subcutaneously.

- **RESULTS**: In this interim analysis, ANX009 administered subcutaneously was well tolerated and demonstrated a favorable safety profile in 5 patients with active lupus nephritis.

- **Conclusions**: These results support further study of anti-C1q therapy in patients with LN.

ACKNOWLEDGMENTS

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REFERENCES


Table 1: Baseline Characteristics

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Figure 1: A Classical Complement Focused View

Figure 2: Study Schematic

Figure 3. ANX009 Decreases C4/C2A Ratio by Patient

Figure 4. ANX009 Blurred the C4/C2A and increased the M1 macrophages in all 5 patients.

Figure 5. ANX009 Decreased PACA Binding in the Kidney

CONCLUSIONS

- In this interim analysis, ANX009 administered subcutaneously was well tolerated and demonstrated a favorable safety profile in 5 patients with active lupus nephritis.

- Immunoblotting of Cq showed that ANX009 decreased Cq activity in sera from all 5 patients.

- ANX009 blocked all downstream markers of consumption and activation, eg, C4, C2, C5, C3, C1q, and C5b-9.

- Treatment of ANX009 via the classical pathway plays a major role in the complement-mediated disease process in LN.

- ANX009 was shown to improve the C4/C2A ratio, which is a marker of classical pathway activation.

- As anticipated, in a short-term (3-week) study with ANX009, patients did not demonstrate consistent changes in UPCT.

- These results support further study of anti-C1q therapy in patients with LN.

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