CTA313, CD19/BCMA dual targeted allo-CAR-TANS cell, Induces Deep B-Cell depletion, Supporting an Immune-Reset Mechanism for Durable Remission in Autoantibody Mediated Diseases

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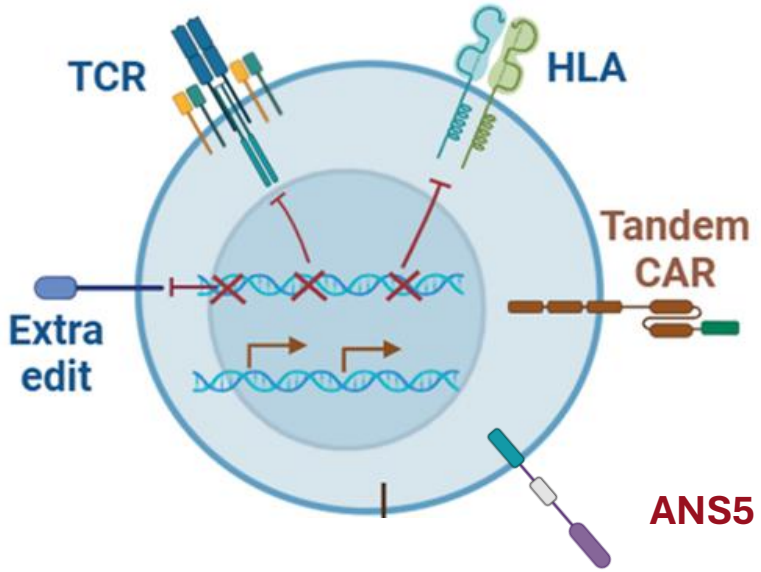
Bioheng Therapeutics is rebranding to Imviva Biotech to reflect global expansion

CTA313 (CD19/BCMA): multi-layer immune evasion and favorable early safety profile

Illustration of CTA313 (CD19/BCMA UCAR-T)



Avoid GvHD	TCR KO
HvGR Strategy 1	Multiple KO to resist host T cells
HvGR Strategy 2	Expressing ANSi to resist host NK

Open-label, single-arm, dose-escalation phase I/II study

LD + CTA313 Single-infusion

3 M/kg → **6 M/kg** → **10 M/kg**

→ **Optimal Dose** → **Dose expansion**

Lymphodepletion (LD): Flu 30, Cy 300 mg/m^2×3d;

Long disease duration, high SLEDAI, and prior biologics exposure

Baseline characteristics of SLE pts (n=28):

- LN in 17 patients
- Median disease duration: 7 years
- Median SLEDAI-2K: 12
- Median # of prior therapies: 5
- Prior biologic use in 6 patients

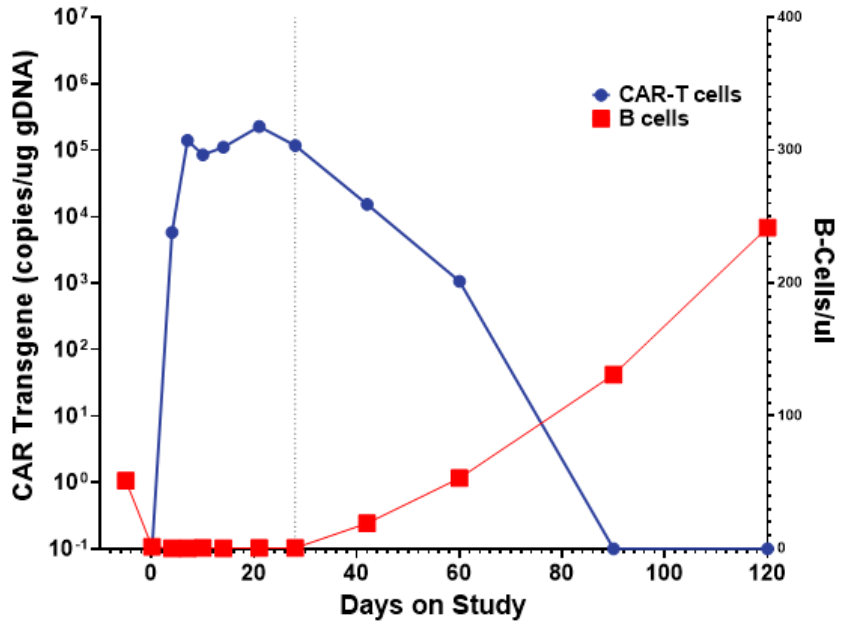
Lower incidence of CRS (all Grade 1) and manageable infection risk

Safety data (n=28)

- G1 CRS only: 12 cases (43%)
- No ICANS/GvHD
- Infections (≥ G3): 3 cases (10.7%)

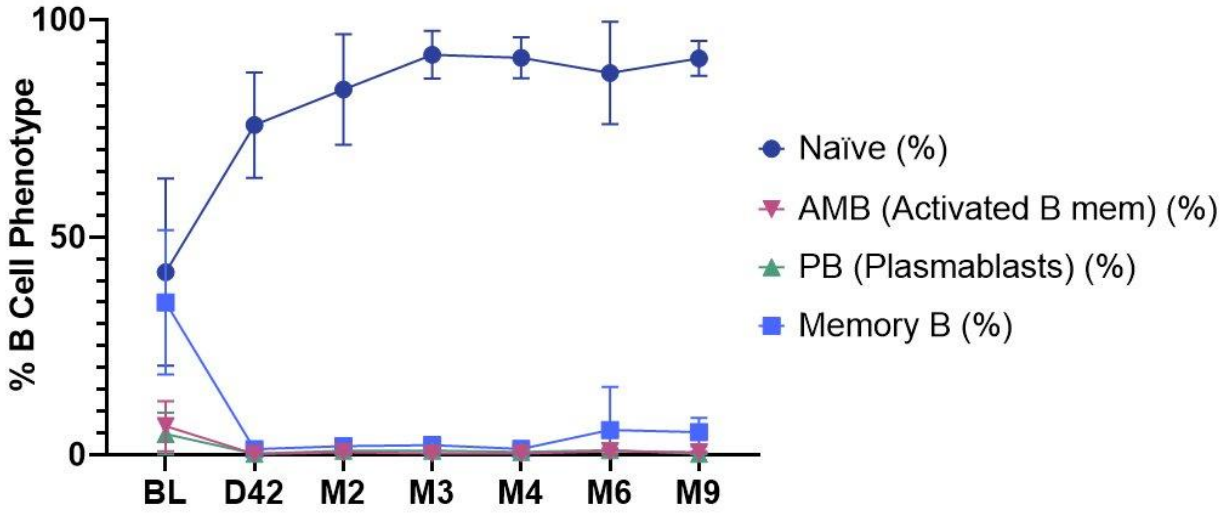
CTA313 hits the therapeutics sweet spot: deep and reversible B-cell depletion, driving sustained clinical benefit

PK: CAR-T expansion versus B-cell clearance



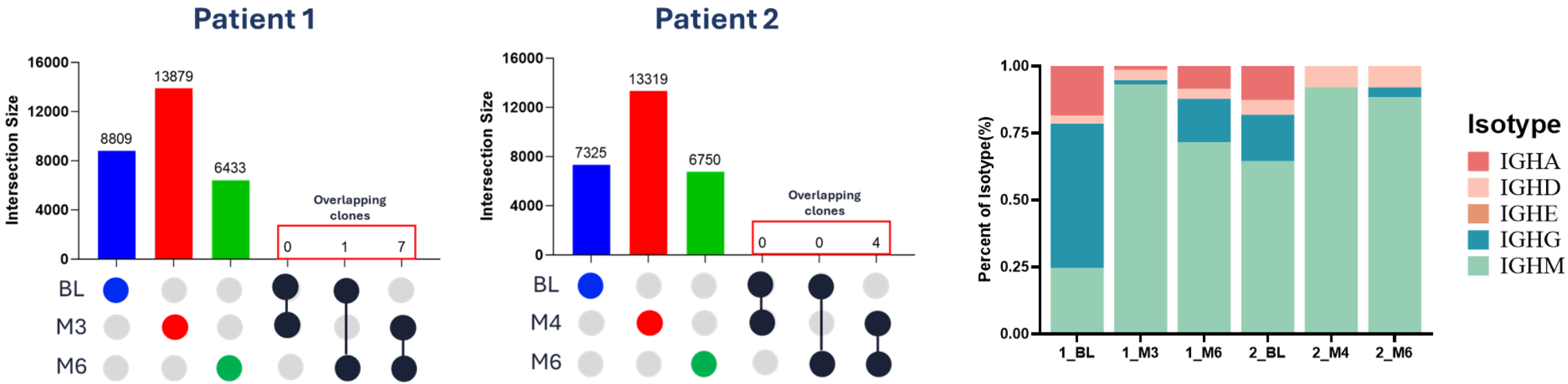
Efficient B-cell depletion with controlled recovery, restoring immune competence after reset.

B-Cell Reset



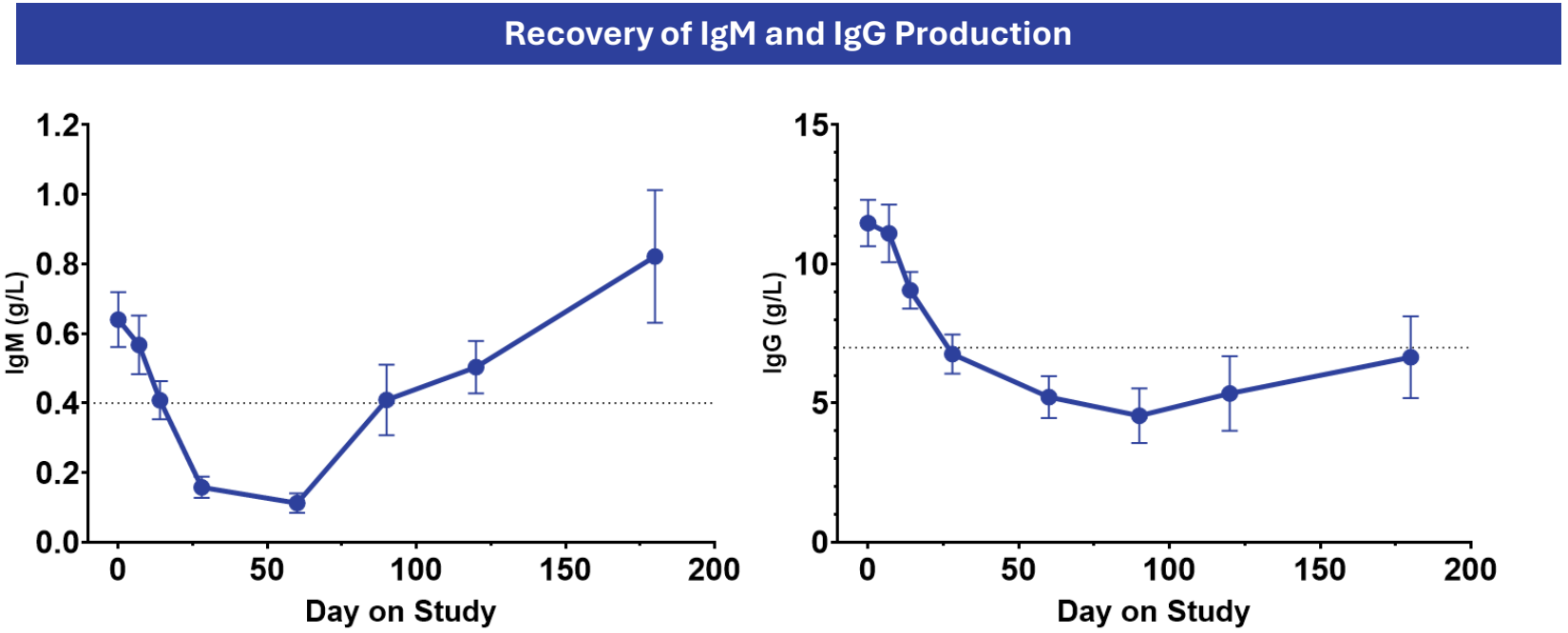
At baseline, both naïve and memory B-cell populations were detectable, whereas after infusion, naïve B cells predominated (>95%) across cohorts and time points, with marked depletion of memory B cells and plasmablasts.

Lack of Overlapping B cell Clones After CTA313 Treatment Indicates Immune Reset



Clonality was determined by scRNAseq. These results indicate these patients had autoimmune B-cell clones that had no overlapping baseline autoimmune B cell clones at both month 2 and 6. These clones were predominantly of the IgM phenotype.

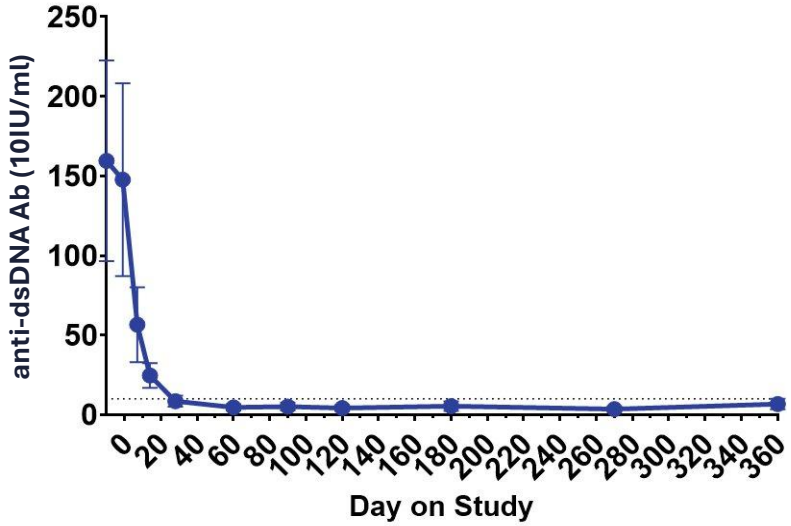
CTA313 Produces Deep, Durable B-cell Depletion Followed By IgM and IgG Antibody Production



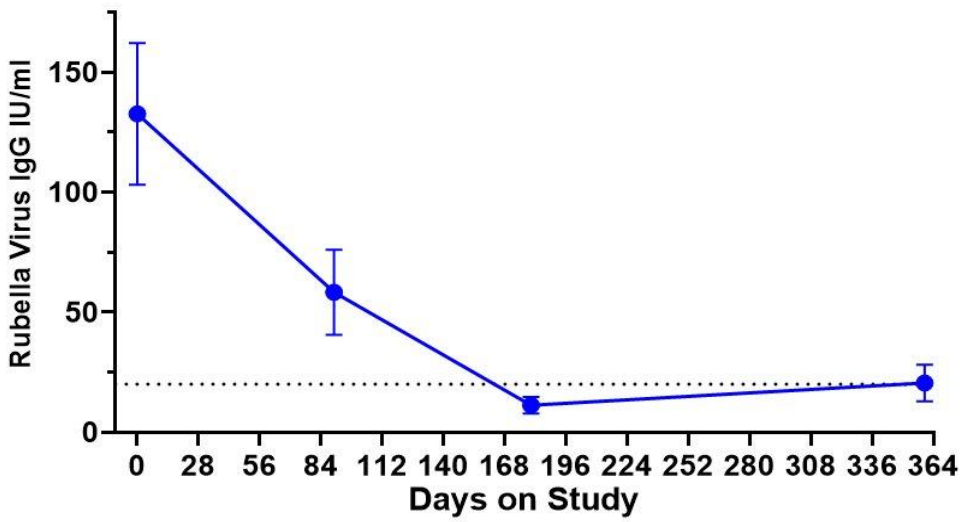
- IgM and IgG antibodies fall below the lower limit of normal after lymphodepletion (day -5 to day 4) and remain low for up to four months coinciding with B cell depletion. Upon B-cell reconstitution, IgM and IgG levels return to normal.

CTA313 Produces Deep, Durable B-cell Depletion Followed By IgM and IgG Antibody Production Without the Recovery of Autoimmune anti-dsDNA Antibodies or Viral Titers

Serologic response - autoantibody

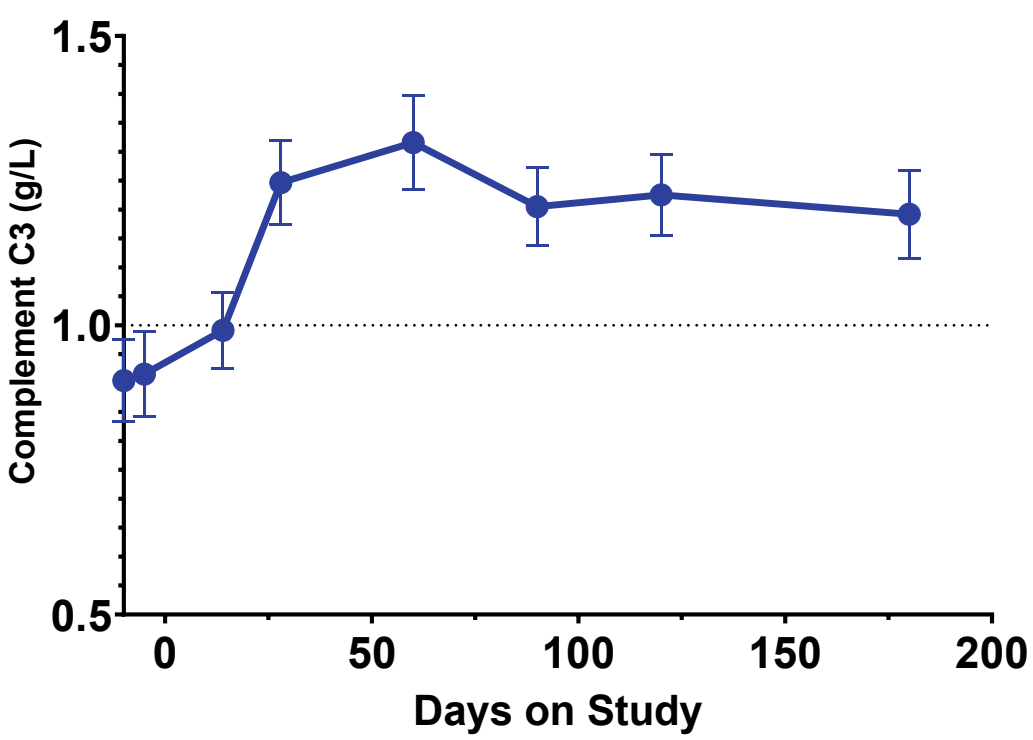


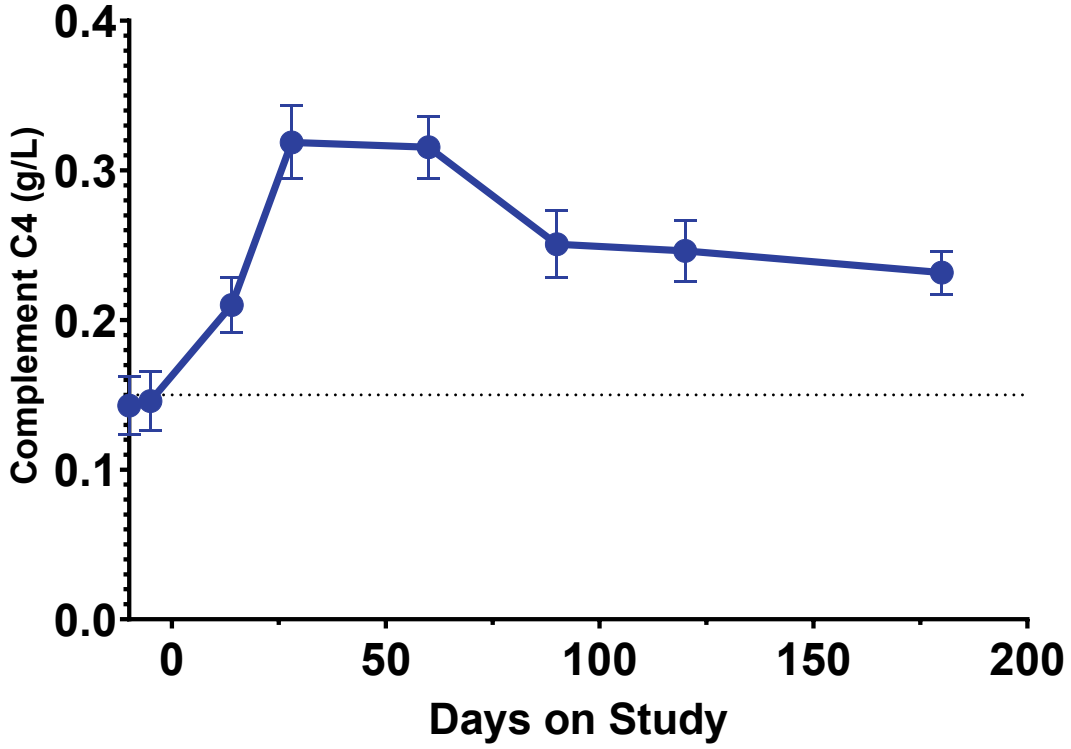
Elimination of Anti-viral Titers



- **Autoimmune anti-dsDNA Abs remain undetected following treatment up to one year**
- **Rubella virus titers fall below detectable levels out to one year**

Complement Recovery After CTA313 Treatment Indicates an Immune Reset

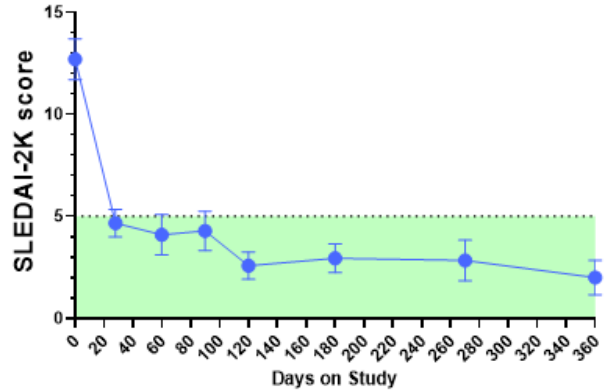




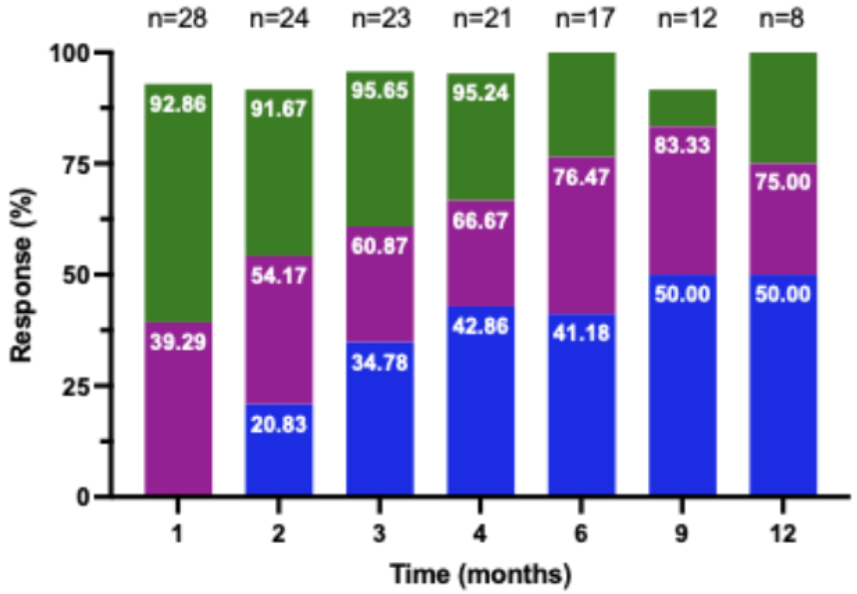
Peripheral complement C3 and C4 levels were below the lower limit of normal before treatment (day -10 to day 0). After CTA313 treatment, complement C3 and C4 levels return to normal.

CTA313 Evolving Responses with Dose and Time Dependent Improvement in Efficacy

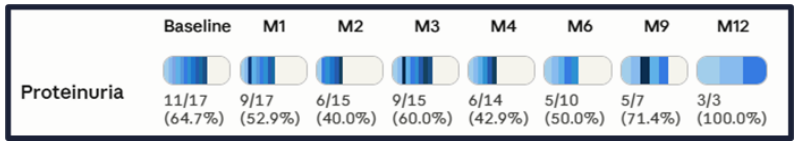
Reduction in SLEDAI-2K and PGA score as early as day 28 persisting for one year



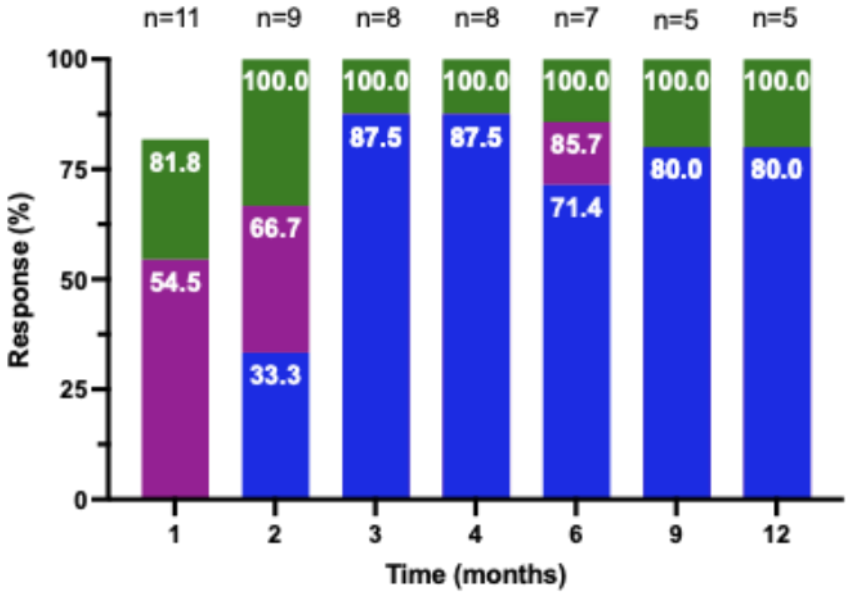
SLE/LN



61% patients achieved immunosuppression-free remission



non-Renal SLE



90% patients achieved immunosuppression-free remission

DORIS (%) | LLDAS (%) | SRI-4 (%)

Conclusions

- CTA313 exhibits an acceptable safety profile in patients with SLE and LN.
- CTA313 demonstrates robust expansion, and long-term persistence exemplary for an allogeneic cell product.
- CTA313 induced profound yet temporal B-cell depletion associated with ongoing elimination of pathogenic autoantibodies, suggestive of immune-reset; marked clinical improvement, with evolving and durable responses in patients with active SLE and LN
- Ongoing clinical studies are further evaluating CTA313 in patients with other B cell-driven autoimmune diseases.
- CTA313 provides a “ready-at-point of care” cell product, which obviates challenges of autologous CAR-T (apheresis, prolonged period off GC/IS Tx risking disease flare), maintains safety, efficacy while increasing pt access to CAR-T therapy in autoimmunity.
- Global study is planned for late 2026