BION-1301 offers disease modifying potential by targeting the underlying multi-immune pathogenesis of IgAN.

**Study Design, Objectives, and Methodology**

- **Study ADU-CL-19** was a 4-week, open label, randomized, placebo-controlled, proof-of-concept, Part 1 study in healthy volunteers (ADU-CL-19) to evaluate the safety, tolerability, and pharmacokinetics (PK) of single SC and IV doses of BION-1301 administered as a single 300mg dosage.

- **ADU-CL-21** was a 4-week, open label, randomized, placebo-controlled, proof-of-concept, Part 2 study in healthy volunteers (ADU-CL-21) to evaluate the safety, tolerability, and pharmacokinetics of BION-1301 administered as a single 300mg dosage over 4 weeks.

**Results**

- **BION-1301** was well tolerated when administered by both SC and IV routes in healthy volunteers.
  - **PK profile of BION-1301** was consistent with previous clinical studies and minimal difference in drug concentrations were observed between administration routes after 1 week.
  - **Mean bioavailability, calculated by dividing individual SC by mean IV AUC**, was 49.7%.
  - **The PK profile of BION-1301** was consistent with previous clinical studies and minimal difference in drug concentrations were observed between administration routes after 1 week.

- **SC route retains 81% of the maximum FAPRIL reduction demonstrated with IV route**
  - **SC** vs **IV**:
    - **Mean (-SD) Percent Changes Relative to Baseline of FAPRIL following Single-SC/V4 SC Administration**: 7.9 ± 1.7% versus 15.0 ± 4.3%.
    - **Mean Change (±SD) Percent Change Relative to Baseline**: 7.9 ± 1.7% versus 15.0 ± 4.3%.
  - **SC administration generates 81% of the maximum fAPRIL reduction compared to IV infusion**.

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**A single 30mcg SC iv dose of BION-1301 provides similar reductions in immunoglobulin**

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**Conclusions**

- **BION-1301** unique MOA offers disease modifying potential by targeting the underlying multi-immune pathogenesis of IgAN.
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