**BACKGROUND**

**KPL-716**

- KPL-716 is an anti-IL-31 monoclonal antibody being investigated by Kiniksa Pharmaceuticals, Ltd. as a potential therapeutic strategy in chronic pruritic diseases.

- IL-31 and Ocsinotan (M) (OSM) signaling are implicated in pruritus, inflammation, and fibrosis (Table 1).

- Inhibition of IL-31 and OSM is a potential therapeutic strategy in chronic pruritic diseases.

**METHODS**

**Study Design**

- Double-blind, randomized, placebo-controlled, single-ascending dose study (Figure 2). 

**Objectives**

- To evaluate safety, tolerability, pharmacokinetics (PK), and immunogenicity in healthy volunteers (Phase 1a) and in patients with atopic dermatitis (Phase 1b).

**Endpoints**

- Primary: Safety and tolerability
- Secondary: PK and anti-drug antibodies (ADA)

**Pharmacokinetics**

- KPL-716 demonstrated dose-dependent elimination, target-mediated drug disposition (TMD), and fibrosis.

**RESULTS**

**Baseline Demographics**

- Table 2: Phase 1b Study Demographics and Disease Characteristics in AD

**Safety**

- Single-dose KPL-716 was well tolerated in healthy volunteers (Table 3) and participants with AD.

**AD Model**

- Decrease in pruritus, erythema, and dermal oedema in the AD model.

**Pharmacokinetics**

- KPL-716 demonstrated dose-dependent elimination, target-mediated drug disposition (TMD). 

**CONCLUSIONS**

- First-in-Human, double-blind, placebo-controlled study of KPL-716 met the primary endpoint:
  - KPL-716 was well tolerated in both healthy volunteers and subjects with AD.
  - KPL-716 engaged its target and demonstrated an early signal of efficacy with pruritus reduction.

- Data support further development of KPL-716 in chronic pruritic diseases.