
**UNITED STATES
SECURITIES AND EXCHANGE COMMISSION**

Washington, D.C. 20549

FORM 8-K

CURRENT REPORT

Pursuant to Section 13 or 15(d) of the Securities Exchange Act of 1934

Date of report (Date of earliest event reported): **September 17, 2018**

Kiniksa Pharmaceuticals, Ltd.

(Exact name of registrant as specified in its charter)

Bermuda

(State or other jurisdiction of
incorporation or organization)

001-730430

(Commission
File Number)

98-1327726

(I.R.S. Employer
Identification No.)

Kiniksa Pharmaceuticals, Ltd.

**Clarendon House
2 Church Street**

Hamilton HM11, Bermuda

+1 (441) 295-5950

(Address, zip code and telephone number, including area code of principal executive offices)

Kiniksa Pharmaceuticals Corp.

100 Hayden Avenue

Lexington, MA, 02421

(781) 431-9100

(Address, zip code and telephone number, including area code of agent for service)

N/A

(Former name, former address and former fiscal year, if changed since last report)

Check the appropriate box below if the Form 8-K filing is intended to simultaneously satisfy the filing obligation of the registrant under any of the following provisions:

- Written communications pursuant to Rule 425 under the Securities Act (17 CFR 230.425)
- Soliciting material pursuant to Rule 14a-12 under the Exchange Act (17 CFR 240.14a-12)
- Pre-commencement communications pursuant to Rule 14d-2(b) under the Exchange Act (17 CFR 240.14d-2(b))
- Pre-commencement communications pursuant to Rule 13e-4(c) under the Exchange Act (17 CFR 240.13e-4(c))

Indicate by check mark whether the registrant is an emerging growth company as defined in Rule 405 of the Securities Act of 1933 (§230.405 of this chapter) or Rule 12b-2 of the Securities Exchange Act of 1934 (§240.12b-2 of this chapter).

Emerging growth company x

If an emerging growth company, indicate by check mark if the registrant has elected not to use the extended transition period for complying with any new or revised financial accounting standards provided pursuant to Section 13(a) of the Exchange Act. x

On September 15, 2018, Kiniksa Pharmaceuticals, Ltd. (the “Company”) (a) presented Phase 1a/1b clinical data for KPL-716 at the 27th European Academy of Dermatology and Venereology Congress during the Late-Breaking News Session, (b) issued a press release in connection therewith, and (c) posted such presentation on its website. A copy of the press release and presentation are furnished with this Current Report on Form 8-K as Exhibit 99.1 and Exhibit 99.2, respectively.

The information contained in this Item 7.01 of this Current Report on Form 8-K and Exhibit 99.1 and Exhibit 99.2 shall not be deemed “filed” for purposes of Section 18 of the Securities Exchange Act of 1934, as amended (the “Exchange Act”) or otherwise subject to the liabilities of that section, nor shall it be deemed incorporated by reference in any filing under the Securities Act of 1933, as amended, or the Exchange Act, regardless of any general incorporation language in such filing and except as expressly provided by specific reference in such filing.

Forward-Looking Statements

The information contained in this Current Report on Form 8-K (inclusive of its Exhibits) contains forward-looking statements within the meaning of the Private Securities Litigation Reform Act of 1995. In some cases, you can identify forward looking statements by terms such as “may,” “will,” “should,” “expect,” “plan,” “anticipate,” “could,” “intend,” “target,” “project,” “contemplate,” “believe,” “estimate,” “predict,” “potential” or “continue” or the negative of these terms or other similar expressions, although not all forward-looking statements contain these identifying words. All statements contained in this Current Report on Form 8-K (inclusive of its Exhibits) that do not relate to matters of historical fact should be considered forward-looking statements, including without limitation, statements regarding objectives of the design of our Phase 1a/1b clinical trial for KPL-716; our conclusions from the Phase 1a/1b clinical trial data; advancement of KPL-716 into multiple chronic pruritic diseases; planning and initiation of new clinical trials; and indications for investigation of our KPL-716 product candidate.

These forward-looking statements are based on management’s current expectations. These statements are neither promises nor guarantees, but involve known and unknown risks, uncertainties and other important factors that may cause our actual results, performance or achievements to be materially different from any future results, performance or achievements expressed or implied by the forward-looking statements, including without limitation, the following: potential for changes between final data and any interim “top-line” and preliminary data we announce; impact of additional data from us or other companies; our potential inability to replicate in later clinical trials positive results from our Phase 1a/1b clinical trial; our potential inability to demonstrate safety and efficacy to the satisfaction of applicable regulatory authorities; potential delays or difficulty in enrollment of patients; potential undesirable side effects caused by our KPL-716 product candidate; our reliance on third parties to manufacture our KPL-716 product candidate; product shortages caused by issues at our third-party manufacturers’ facilities; our reliance on third parties as the sole source of supply of the active ingredient, drug product and drug substance used in our KPL-716 product candidate; and our reliance on third parties to conduct our research, clinical trials, and other trials for our KPL-716 product candidate.

These and other important factors discussed under the caption “Risk Factors” in our Quarterly Report on Form 10-Q filed with the Securities and Exchange Commission (“SEC”) on August 7, 2018 and our other reports subsequently filed with or furnished to the SEC could cause actual results to differ materially from those indicated by the forward-looking statements made in this Current Report on Form 8-K. Any such forward-looking statements represent management’s estimates as of the date of this Current Report on Form 8-K (inclusive of its Exhibits). While we may elect to update such forward-looking statements at some point in the future, we disclaim any obligation to do so, even if subsequent events cause our views to change. These forward-looking statements should not be relied upon as representing our views as of any date subsequent to the date of this Current Report on Form 8-K.

Item 9.01. Financial Statements and Exhibits.

(d) Exhibits

<u>Exhibit No.</u>	<u>Description</u>
99.1	Press Release issued by Kiniksa Pharmaceuticals, Ltd. dated September 15, 2018
99.2	Kiniksa Pharmaceuticals, Ltd. 27th EADV Congress Later-Breaker Presentation for KPL-716

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SIGNATURES

Pursuant to the requirements of the Securities Exchange Act of 1934, the registrant has duly caused this report to be signed on its behalf by the undersigned hereunto duly authorized.

KINIKSA PHARMACEUTICALS, LTD.

Date: September 17, 2018

By: /s/ Thomas Beetham
Thomas Beetham
Executive Vice President, Chief Legal Officer

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Kiniksa Presents KPL-716 Clinical Data at the 27th European Academy of Dermatology and Venereology

-Single-doses were well-tolerated and showed reduction in pruritus -

- Data support plans for advancement into multiple chronic pruritic diseases, including prurigo nodularis -

HAMILTON, BERMUDA — September 15, 2018 — Kiniksa Pharmaceuticals, Ltd. (Nasdaq: KNSA) (“Kiniksa”), a biopharmaceutical company focused on discovering, acquiring, developing and commercializing therapeutic medicines for patients with significant unmet medical need, today presented Phase 1a/1b clinical data for KPL-716, an investigational fully-human monoclonal antibody that targets oncostatin M receptor beta (OSMR β), at the 27th European Academy of Dermatology and Venereology (EADV) Congress. In this First-in-Human clinical trial, single intravenous (IV) and subcutaneous (SC) doses of KPL-716 were well-tolerated in both adult healthy volunteers and adult subjects with moderate-to-severe atopic dermatitis experiencing moderate-to-severe pruritus. KPL-716 also demonstrated a reduction in pruritus. The results support Kiniksa’s plans for expanding clinical development into multiple chronic pruritic diseases, including prurigo nodularis.

Dr. Zaneh Mikhak, Senior Director, Clinical Research and Development at Kiniksa, delivered an oral presentation entitled “First-In-Human Study of KPL-716, Anti-Oncostatin M Receptor Beta Monoclonal Antibody, in Healthy Volunteers and Subjects with Atopic Dermatitis” during the Late-Breaking News Session. The materials are available through the Investors and Media section of Kiniksa’s website (www.kiniksa.com).

“Data from the single-dose cohorts of the placebo-controlled Phase 1a/1b of KPL-716 achieved the goals established for the study,” said Sanj K. Patel, Chief Executive Officer and Chairman of the Board of Kiniksa. “The results provided us with data on the safety and tolerability of KPL-716 as well as the anti-pruritic effect of the drug. We believe KPL-716 has the potential to be an effective treatment option for patients with pruritic diseases where there is unmet medical need.”

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The Phase 1a/1b clinical trial utilized a double-blind, randomized, placebo-controlled, single-ascending-dose, sequential-group design to evaluate the safety, tolerability, pharmacokinetics and immunogenicity of KPL-716 in healthy volunteers and subjects with atopic dermatitis following IV or SC administration. Atopic dermatitis served as a proxy for IL-31-driven pruritic diseases, including prurigo nodularis.

In total, 50 healthy volunteers and 32 subjects with moderate-to-severe atopic dermatitis experiencing moderate-to-severe pruritus received a single dose of KPL-716 or placebo in the Phase 1a/1b clinical trial, with the top dose of 20 mg/kg IV in healthy volunteers and 7.5 mg/kg IV in subjects with atopic dermatitis. There was a seven-day wash out period of prior therapies for all subjects with atopic dermatitis before treatment, and topical corticosteroids (TCS) were not allowed through Day 28. All subjects were given TCS to use as needed after Day 28 and rescue medication was provided for atopic dermatitis flares throughout the study.

KPL-716 was well-tolerated by all subjects, no dose-limiting toxicities were observed, and there were no serious adverse events.

KPL-716 showed dose-dependent elimination consistent with a target mediated drug disposition profile and was still detectable at least eight weeks after the high dose of 7.5 mg/kg IV in subjects with atopic dermatitis. The available pharmacokinetic and bioavailability data are supportive of SC dosing regimens to be tested in subsequent studies of a single injection once every other week or once monthly.

A single dose of KPL-716 7.5 mg/kg IV in subjects with moderate-to-severe atopic dermatitis (n=10) versus pooled placebo IV recipients (n=10) provided evidence of target engagement and an early signal of efficacy for KPL-716 in reducing pruritus:

- Mean percentage change in weekly-average Worst-Itch Numeric Rating Scale (WI-NRS) decreased by 40.4% in KPL-716 recipients compared to a 17.6% decrease in placebo recipients at Day 28 in the absence of concomitant TCS.
- Mean percentage change in Pruritus Visual Analog Scale (VAS) decreased by 55.4% in KPL-716 recipients compared to a 10.4% decrease in placebo recipients at Day 28 in the absence of concomitant TCS.
- 50% of KPL-716 recipients demonstrated a \geq 4-point reduction in weekly-average WI-NRS, compared to 10% of placebo recipients at Day 28 in the absence of concomitant TCS.

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- The maximum decrease in WI-NRS at Day 28 in the absence of concomitant TCS was \geq 8-points in KPL-716 recipients compared to a maximum decrease of 4 points in placebo recipients.
- KPL-716 appeared to demonstrate a persistent effect on weekly-average WI-NRS in the period after Day 28 through Day 56, during which concomitant TCS use was permitted.

- Concordant with the effect on pruritus, KPL-716 recipients reported improved sleep, as evidenced by a 59.5% decrease in sleep-loss VAS compared to a 2.3% decrease in placebo recipients at Day 28 in the absence of concomitant TCS.
- The mean percentage change in Eczema Area and Severity Index (EASI; a standardized measure of atopic dermatitis disease severity) decreased by 42.3% in KPL-716 recipients compared to a 25% decrease in placebo recipients at Day 28 in absence of concomitant TCS.

“The KPL-716 Phase 1a/1b results met a high hurdle for success, as the placebo-controlled, single-dose safety and pharmacokinetics study also demonstrated reduction in pruritus,” said John F. Paolini, MD, PhD, Chief Medical Officer of Kiniksa. “We are now considering advancement of KPL-716 into multiple chronic pruritic diseases, including prurigo nodularis. Additionally, the observed reduction in EASI scores after only a single dose of KPL-716 is encouraging. Our ongoing repeat-single-dose trial in atopic dermatitis subjects will provide longer-term exposures and data on these inflammatory disease response markers.”

About KPL-716

KPL-716 is an investigational fully-human monoclonal antibody that targets oncostatin M receptor beta (OSMR β), which mediates signaling of IL-31 and oncostatin M (OSM), two key cytokines implicated in pruritus, inflammation and fibrosis. Kiniksa believes KPL-716 to be the only monoclonal antibody in development that targets both pathways simultaneously.

About Kiniksa

Kiniksa is a biopharmaceutical company focused on discovering, acquiring, developing and commercializing therapeutic medicines for patients suffering from debilitating diseases with significant unmet medical need. Kiniksa has a pipeline of product candidates across various stages of development, currently focused on autoinflammatory and autoimmune conditions. For more information, please visit www.kiniksa.com.

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Forward-Looking Statements

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***Every Second Counts!*TM**

Kiniksa Investor and Media Contact

Mark Ragosa
(781) 430-8289
mragosa@kiniksa.com

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First-In-Human Study of KPL-716, Anti-Oncostatin M Receptor Beta Monoclonal Antibody, in Healthy Volunteers and Subjects With Atopic Dermatitis

Zamaneh Mikhak¹, Joel M. Neutel², Robert Bissonnette³, Dareen Siri⁴, Thomas Wade⁵, Stephen K. Tyring⁶, Eben Tessari¹, Rohan Gandhi¹, Fang Fang¹, John F. Paolini¹

¹Kiniksa Pharmaceuticals Corp., Lexington, Massachusetts, USA; ²Orange County Research Center, Tustin, California, USA; ³Innovaderm Research, Inc., Montreal, Quebec, Canada; ⁴Sneeze, Wheeze and Itch Associates, Normal, Illinois, USA; ⁵QPS Miami Research Associates, Miami, Florida, USA; ⁶Houston Skin Associates, Houston, Texas, USA

Presented at: The 27th Congress of the European Academy of Dermatology and Venereology; September 12–16, 2018; Paris, France

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Acknowledgements and Disclosures

Acknowledgments:

- **Study Sponsor:** Kiniksa Pharmaceuticals, Ltd.

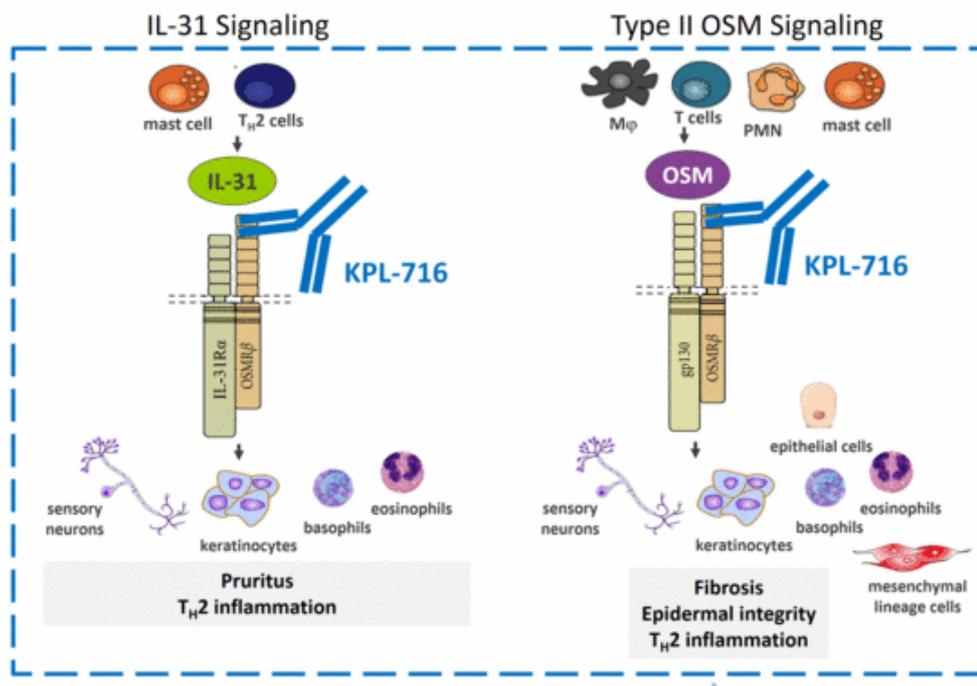
Disclosures:

- **Zamaneh Mikhak, Eben Tessari, Rohan Gandhi, Fang Fang, John F. Paolini:** Employees at Kiniksa Pharmaceuticals Corp.
- **Robert Bissonnette:** Investigator, Consultant, Advisory Board Member, Speaker for and/or receives honoraria from Aquinox Pharma, Antiobix, Asana, Astellas, Brickell Biotech, Dermavant, Dermira, Dignity Sciences, Eli Lilly, Galderma, Glenmark, GSK-Stiefel, Hoffman-LaRoche Ltd, Leo Pharma, Neokera, Pfizer, Regeneron, Sienna, and Vitae; Shareholder of Innovaderm Research; Investigator for Kiniksa Pharmaceuticals, Ltd.
- **Joel M. Neutel:** Investigator for Kiniksa Pharmaceuticals, Ltd.
- **Dareen Siri:** Investigator for Regeneron, Pfizer, AnaptysBio, Vanda, Kiniksa Pharmaceuticals, Ltd., Speaker, Advisory Board, and Steering Committee for Regeneron /Sanofi.
- **Stephen K. Tyring:** Investigator for Abbvie, Aclaris, BMS, BI, Celgene, Dermik, Galderma, GSK, Janssen, Leo, Merck, Novartis, Ortho, Pfizer, Regeneron, Roche, Kiniksa Pharmaceuticals, Ltd.
- **Thomas Wade:** Investigator for Kiniksa Pharmaceuticals, Ltd.

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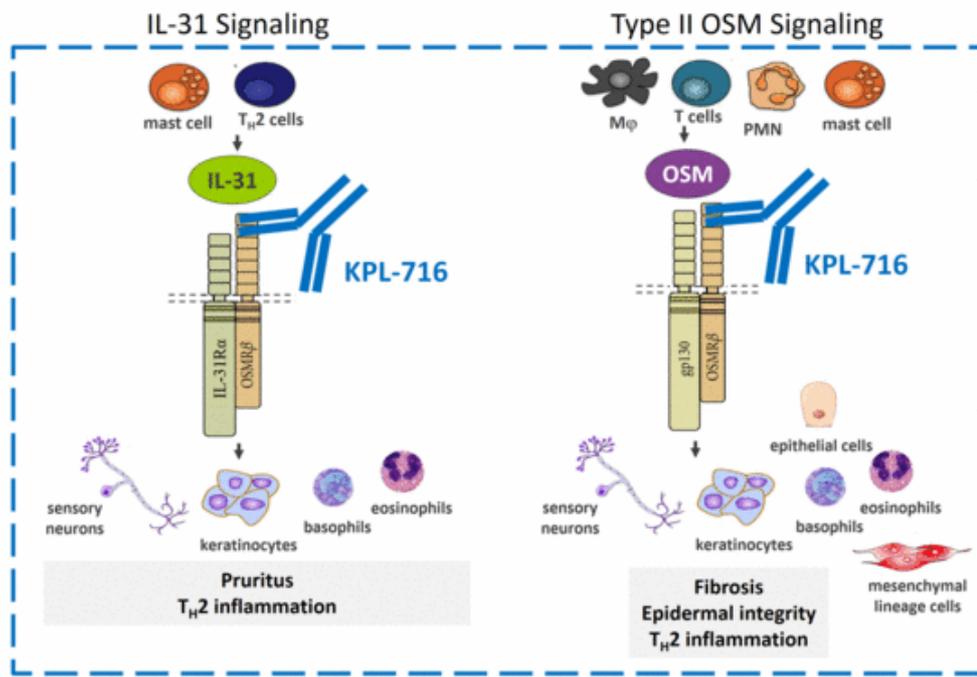
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KPL-716 simultaneously inhibits both IL-31 and Oncostatin M (OSM) pruritic/inflammatory signaling



By binding a single epitope, KPL-716 simultaneously inhibits both IL-31 and OSM signaling, two pathways implicated in pruritus, inflammation, and fibrosis.

KPL-716 does not inhibit critical hematopoiesis signaling through OSM/LIFR



Atopic Dermatitis (AD) is a proxy for IL-31-driven pruritic diseases

Role of IL-31 is well-established in pruritus and AD

- IL-31 levels are elevated in AD and correlate with disease severity¹⁻³
- Keratinocytes and macrophages express IL-31R α , and circulating CLA⁺ T cells express IL-31 in AD⁴
- Basophils release IL-31, and IL-31 increases IL-4 and IL-13 production in basophils; upregulation inhibited by anti-IL-31R α and anti-OSMR β ⁵
- Anti-IL-31R α treatment reduced pruritus in AD⁶

OSM plays an important role in T_H2 inflammation, epidermal integrity, and fibrosis

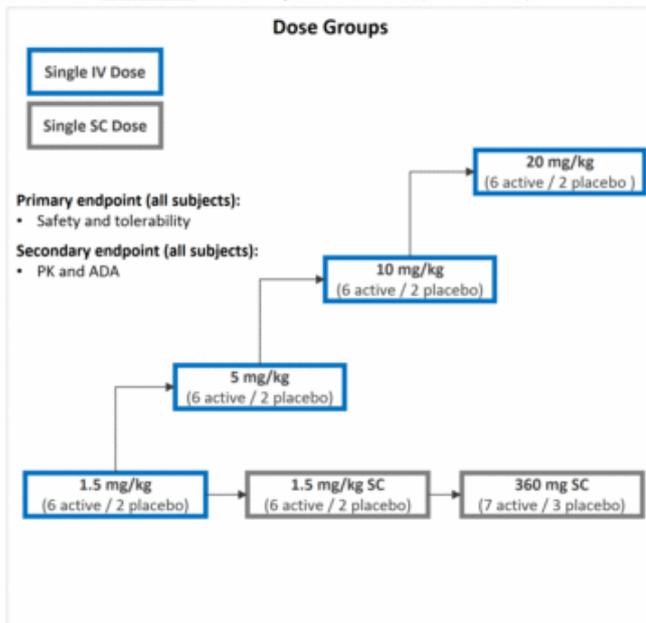
- Increases IL-4R α and IL-13R α production⁸⁻¹³
- Increases IL-4 production; synergizes with IL-4 and IL-13 to increase eotaxin production in fibroblasts and airway smooth muscle cells^{8, 10-14}
- Modulates genes important in keratinocyte activation and differentiation^{8, 9}
- Levels are elevated in fibrotic diseases, and OSM over-expression in animal models results in fibrotic changes^{11, 15}

1) Raap et al. JACI, 2008; 2) Kim et al. Ann Derm, 2011; 3) Nobbe et al. Acta Derm Venerol, 2012; 4) Bilsborough et al. JACI, 2006; 5) Raap et al. Clin Exp Allergy, 2017; 6) Nemoto et al. BJD, 2016; 7) Ruzicka et al. JEM, 2017; 8) Gazel et al. JID, 2006; 9) Boniface et al. JI, 2007; 10) Fritz et al. JI, 2011; 11) Mozaffarian et al. JI, 2008; 12) Fritz et al. Exp Cell Rsch, 2009; 13) Kwofle et al. Resp Rsch, 2015. 14) Botelho et al. JI, 2013; 15) Wong et al. Lab Investigation; 2014.

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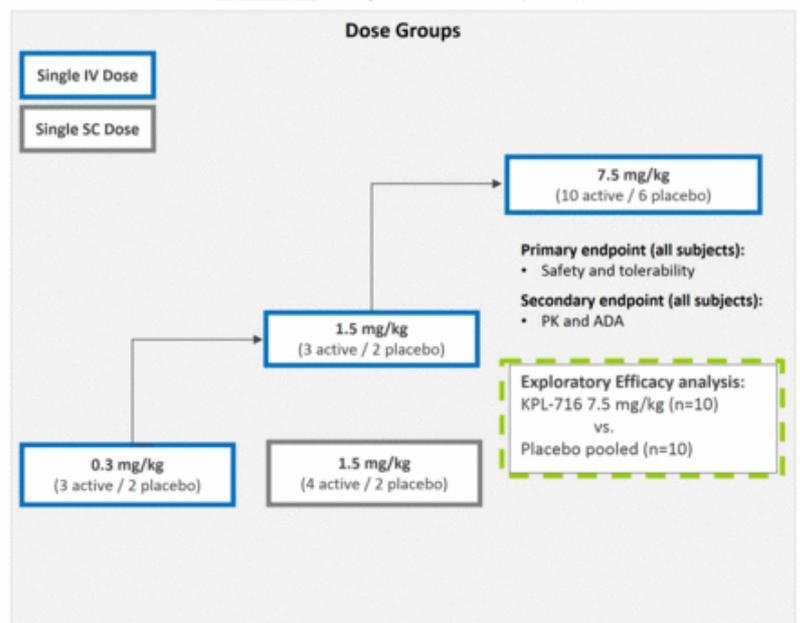
KPL-716 Phase 1a/1b Study Design: Double-blind, placebo-controlled, single-ascending-dose

Phase 1a: Healthy volunteers (HV; n=50)



AD = atopic dermatitis, IV = intravenous, SC = subcutaneous, PK = pharmacokinetics, ADA = anti-drug antibodies

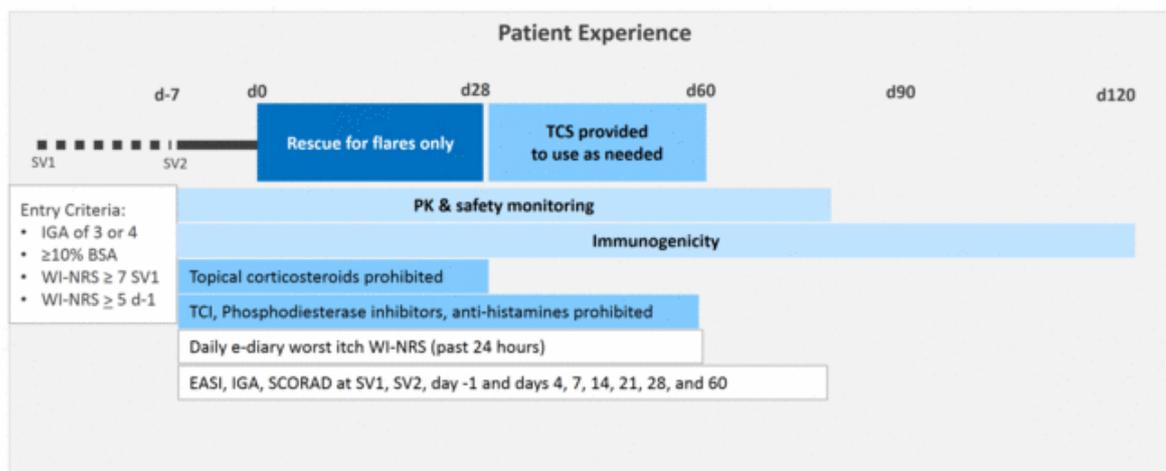
Phase 1b: Subjects with AD (n=32)



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Phase 1b: Washout Design, KPL-716 Monotherapy

Phase 1b: Subjects with AD (n=32)



- Primary endpoint:**
- Safety and tolerability
- Secondary endpoint:**
- PK and ADA
- Exploratory endpoints:**
- Target engagement
 - Early Signal of Efficacy

- Systemic corticosteroids, immunosuppressants, immunomodulators, and phototherapy were prohibited from 4 weeks or 5 half-lives before SV2 until d60
- Topical calcineurin inhibitors (TCI), topical phosphodiesterase inhibitors, and anti-histamines were prohibited from d-7 until d60
- Topical corticosteroids (TCS) were prohibited from d-7 until d28

AD = atopic dermatitis, IV = intravenous, SC = subcutaneous, PK = pharmacokinetics, ADA = anti-drug antibodies, IGA = Investigator's Global Assessment (severity scale), WI-NRS = Worst Itch Numerical Rating Scale, BSA = Body Surface Area, EASI = Eczema Area and Severity Index, SCORAD = Scoring atopic dermatitis (severity scale), SV1 = Screening Visit #1, SV2 = Screening Visit #2

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Baseline Parameters were Balanced

Baseline demographics/disease characteristics: AD	KPL-716 7.5 mg/kg IV	Placebo Pooled IV
Age, mean (SD), years	29.7 (11.2)	41.7 (10.9)
Male, %	50	70
White, %	70	70
Elevated IgE, %	60	60
History of any allergic disease, %	40	60
#AD flares in past year, mean (SD)	28.1 (41.6)	3.7 (3.5)
Body surface area affected by AD, mean (SD)	24.2 (8.0)	34.1 (28.0)
Weekly average WI-NRS, mean (SD)	8.0 (1.3)	8.2 (0.7)
Total EASI, mean (SD)	19.9 (7.6)	25.3 (14.1)
Total SCORAD, mean (SD)	66.7 (10.7)	60.7 (13.7)
IGA=3, %	80	80
IGA=4, %	20	20

Baseline is defined as the last measurement prior to dosing.

AD = atopic dermatitis, IV = intravenous, IGA = Investigator's Global Assessment (severity scale), WI-NRS = Worst Itch Numerical Rating Scale, EASI = Eczema Area and Severity Index, SCORAD = Scoring atopic dermatitis (severity scale)

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KPL-716 was Well-Tolerated

- No Deaths
- No SAEs
- No Discontinuations due to AEs
- No Infusion Reactions
- No Injection Site Reactions
- No Thrombocytopenia
- No Peripheral Edema
- No Conjunctivitis
- Drug-Related Treatment Emergent Adverse Events (DR-TEAEs) infrequent and not related to dose

Healthy volunteers

AE	KPL-716 (IV)					Placebo (IV)	KPL-716 (SC)		Placebo (SC)
	1.5 mg/kg n=6	5 mg/kg n=6	10 mg/kg n=6	20 mg/kg n=6	Pooled n=8	1.5 mg/kg n=6	360 mg n=7	Pooled n=5	
DR-TEAE	0	Mild headache (1)	0	0	0	Mild flushing (1)	Mild anemia (1)	0	

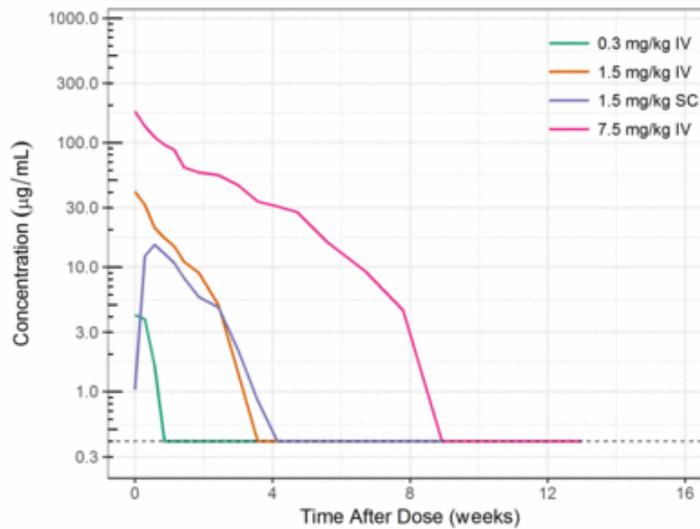
Subjects with atopic dermatitis

AE	KPL-716 (IV)			Placebo (IV)	KPL-716 (SC)	Placebo (SC)
	0.3 mg/kg n=3	1.5 mg/kg n=3	7.5 mg/kg n=10	Pooled n=10	1.5 mg/kg n=4	Pooled n=2
DR-TEAE	0	Mild headache (1), Decreased appetite (1)	Moderate dizziness (1)	Mild somnolence (1)	Mild dizziness (1)	0
AD flare	1	0	2	3	0	0
Study day of AD flare	7	N/A	14, 20	1, 5, 45	N/A	N/A

*The only moderate DR-TEAE occurred after a protocol violation.

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KPL-716 demonstrated dose-dependent elimination (TMDD)



TMDD: Target-Mediated Drug Disposition

Exploratory Efficacy Endpoints and Analysis Plan

Efficacy Analysis:

- 10 KPL-716 subjects (7.5 mg/kg IV) versus 10 placebo subjects (pooled IV) from baseline to Day 28
- “Last Observation Carried Forward” approach used for data values after rescue medication administered. Subject was considered non-responder after rescue (responder analysis).
 - Two KPL-716: 2 AD flares (d15 and d21)
 - Three placebo: 2 AD flares (d3, d14), 1 anti-histamine use for upper respiratory infection (d26)
- Similar results obtained if data values after rescue medication administration were included or excluded

Efficacy Endpoints:

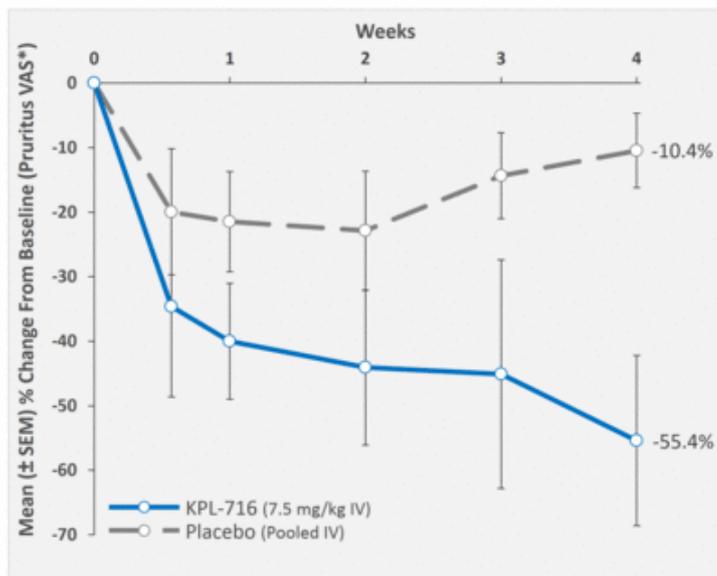
- Pruritus:
 - Weekly average of daily WI-NRS (worst itch in past 24 hours) collected by daily eDiary
 - Pruritus Visual Analog Scale, a component of SCORAD (average itch in past 3 days) collected at study visits
- Sleep loss VAS:
 - A component of SCORAD (average sleep loss in past 3 nights)
- Eczema Area Severity Index (EASI)

AD = atopic dermatitis, IV = intravenous, WI-NRS = Worst Itch Numerical Rating Scale, EASI = Eczema Area and Severity Index, SCORAD = Scoring atopic dermatitis (severity scale)

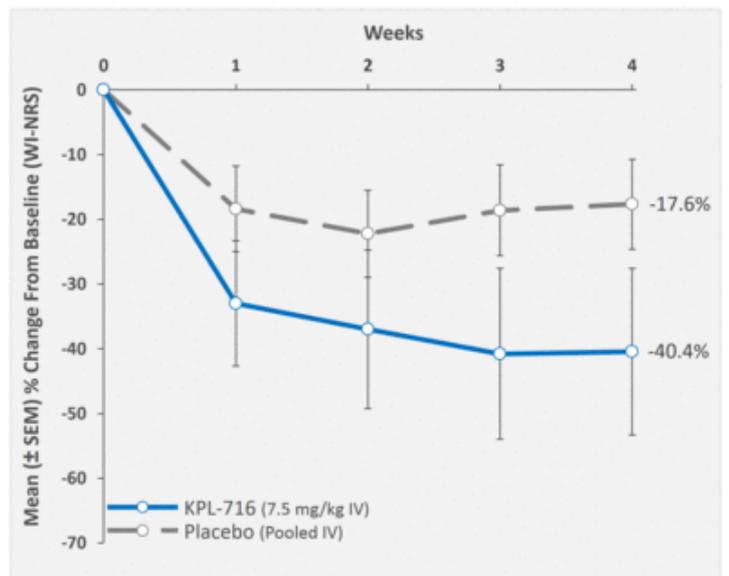
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KPL-716 (single dose) reduced pruritus versus Placebo (28 day monotherapy period)

Pruritus Visual Analog Scale (VAS)*



Weekly Average of “Worst Itch Numerical Rating Scale” (WI-NRS)



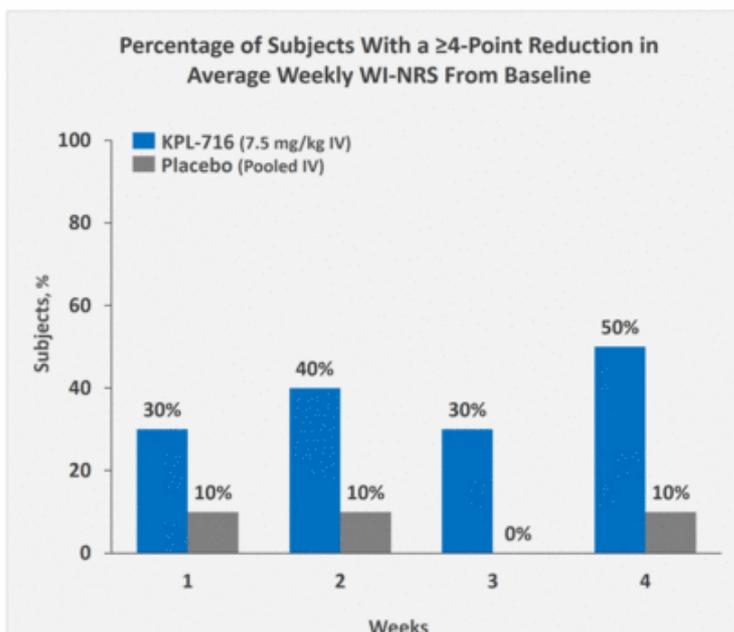
*A component of SCORAD.

In subjects who received rescue medication, last observation was carried forward. Two KPL-716 recipients (d15, d 21) and three placebo recipients (d3, d14, d26).

SCORAD = Scoring atopic dermatitis (severity scale)

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KPL-716 (single dose) reduced WI-NRS by ≥ 4 Points versus Placebo (28 day monotherapy period)



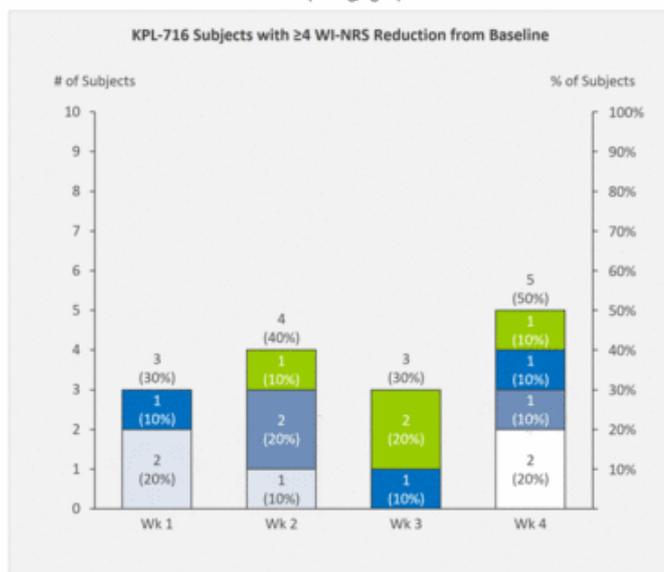
Subject was considered non-responder after rescue. Two KPL-716 recipients (d15, d 21) and three placebo recipients (d3, d14, d26).

WI-NRS = Worst Itch Numerical Rating Scale

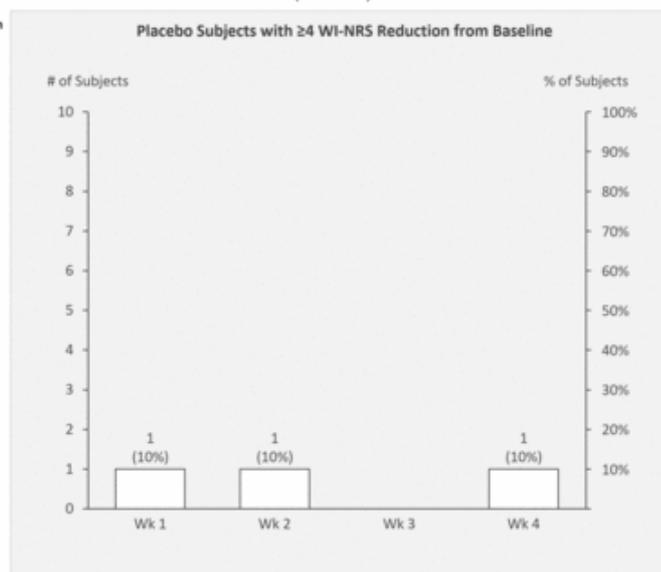
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KPL-716 (single dose) reduced WI-NRS to a greater magnitude versus Placebo (28 day monotherapy period)

KPL-716
(7.5mg/kg IV)



Placebo
(Pooled IV)

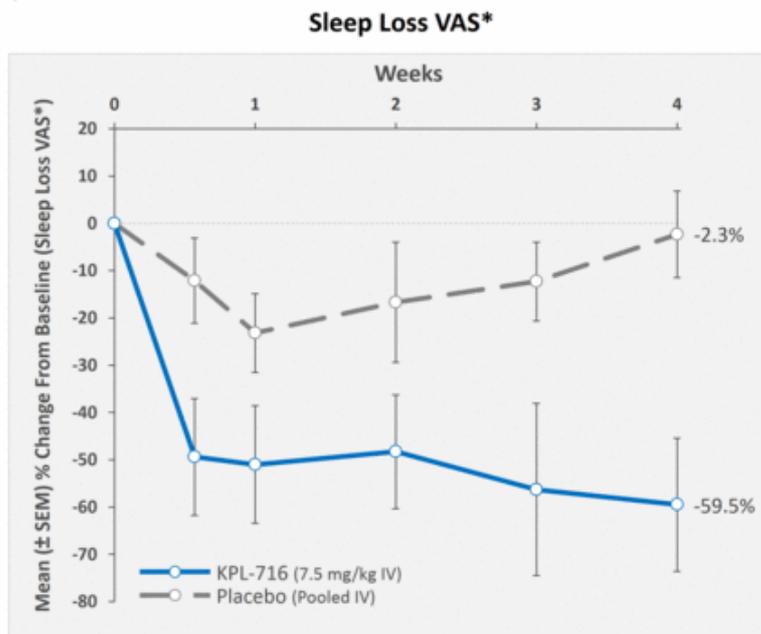


Subject was considered non-responder after rescue. Two KPL-716 recipients (d15, d 21) and three placebo recipients (d3, d14, d26).

WI-NRS = Worst Itch Numerical Rating Scale

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KPL-716 (single dose) reduced Sleep Loss, an important QoL parameter, versus Placebo (28 day monotherapy period)



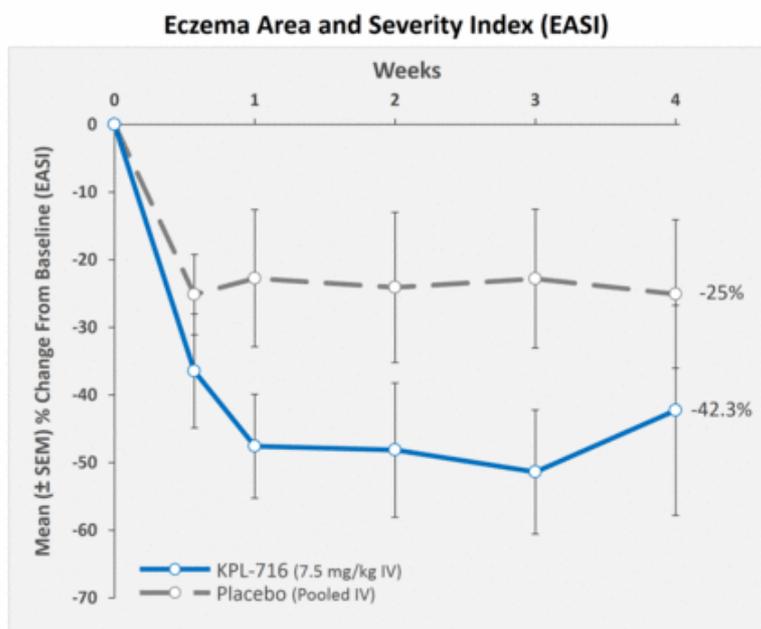
*A component of SCORAD.

QoL = Quality of Life, VAS = Visual Analog Scale,
SCORAD = Scoring atopic dermatitis (severity scale)

In subjects who received rescue medication, last observation was carried forward. Two KPL-716 recipients (d15, d 21) and three placebo recipients (d3, d14, d26).

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KPL-716 (single dose) reduced Atopic Dermatitis Disease Severity versus Placebo (28 day monotherapy period)



In subjects who received rescue medication, last observation was carried forward. Two KPL-716 recipients (d15, d 21) and three placebo recipients (d3, d14, d26).

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Summary

- 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
 - Reduction in disease severity (EASI) and sleep loss were also demonstrated
 - Repeated-Single-Dose study in subjects with AD is ongoing; longer duration will provide additional efficacy data
- Data support further development of KPL-716 in chronic pruritic diseases

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Joel M. Neutel, MD

Orange Country Research Center
Tustin, California, USA

Robert Bissonnette, MD

Innovaderm
Montreal, Quebec, Canada

Stephen K. Tyring, MD

Houston Skin Associates
Houston, Texas, USA

Thomas Wade, MD

QPS-MRA, LLC
Miami, Florida, USA

Dareen Siri, MD

Sneeze, Wheeze and Itch Associates
Normal, Illinois, USA

Iftikhar Hussain, MD

Vital Prospects
Tulsa, Oklahoma, USA

Douglas Denham, DO, CPI

Clinical Trials of Texas, Inc.
San Antonio, Texas, USA

Jamshid Lofti, MD

Clinical Trial Network
Houston, Texas, USA

Jonathan S. Dosik, MD

TKL Research
Fair Lawn, New Jersey, USA

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