
**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 13, 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
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+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 August 29, 2018, Kiniksa Pharmaceuticals, Ltd. (the “Company”) issued a press release indicating that it was selected to present Phase 1a/1b clinical data for KPL-716 on Saturday 15, 2018 at the 27th European Academy of Dermatology and Venereology (“EADV”) Congress during the Late-Breaking News Session (“Late-Breaker”). On September 13, 2018, the EADV posted the Company’s Late-Breaker Abstract submission on its website. A copy of the Company’s Late-Breaker Abstract submission is furnished with this Current Report on Form 8-K as Exhibit 99.1.

The information contained in this Item 7.01 of this Current Report on Form 8-K and Exhibit 99.1 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 Exhibit 99.1 to this Current Report on Form 8-K 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 Exhibit 99.1 to this Current Report on Form 8-K 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 our Phase 1a/1b clinical trial data; and proposed 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; our reliance on third parties to manufacture our KPL-716 product candidate; our potential inability to replicate in later clinical trials positive results from our Phase 1a/1b clinical trial.

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 Exhibit 99.1 to 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. 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

Exhibit No.	Description
99.1	Kiniksa Pharmaceuticals, Ltd. 27th EADV Congress Late-Breaker Abstract submission 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 13, 2018

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

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

Introduction & Objectives: KPL-716 is a fully-human monoclonal antibody targeting Oncostatin M receptor beta (OSMR β), the shared receptor subunit for IL-31 and Oncostatin M (OSM) signaling. Its novel dual mechanism inhibits both the IL-31 pruritus pathway and the OSM pathway, implicated in TH2 inflammation and fibrosis. This First-In-Human, placebo (PBO)-controlled Phase 1a/1b study of adult healthy volunteers (HV) and adult subjects with atopic dermatitis (AD) evaluated the safety and tolerability of single-dose KPL-716 and used AD as a proxy for IL-31-driven pruritic diseases to assess target engagement and Early Signal of Efficacy.

Materials & Methods: This randomized, double-blind, PBO-controlled, single-ascending dose study of KPL-716 enrolled adult HVs and adult subjects with moderate to severe AD (Investigator Global Assessment [IGA] score of 3 or 4, body surface area [BSA] \geq 10%) experiencing moderate to severe pruritus (worst itch Numerical Rating Scale [WI-NRS] \geq 7 at screening). Intravenous (IV) or subcutaneous (SC) KPL-716 was administered in escalating dose cohorts: HV IV: 1.5, 5, 10, and 20 mg/kg; HV SC: 1.5 mg/kg and 360 mg; AD IV: 0.3, 1.5 and 7.5 mg/kg; AD SC: 1.5 mg/kg.

Safety and tolerability were assessed prior to dose escalation. Prohibited medications included topical corticosteroids (TCS) from Day -7 to Day 28; rescue medication was provided for AD flares. All subjects were given TCS to use as needed after Day 28.

Safety and tolerability data included vital signs, physical examination, ECG, laboratory measures, and adverse events (AEs). KPL-716 target engagement and clinical pharmacodynamic (PD) data included daily e-diary WI-NRS and periodic Sleep-Loss Visual Analogue Scale (VAS) until Day 60. Weekly average of daily WI-NRS was calculated.

Results: A single dose of KPL-716 was administered to 50 HVs (IV - 24 active: 8 PBO; SC - 13 active: 5 PBO) and 32 subjects with AD (IV - 16 active: 10 PBO; SC - 4 active: 2 PBO). Baseline demographics were balanced across dose groups. No deaths, SAEs, or discontinuations due to AEs occurred. Drug-related treatment-emergent AEs were infrequent and showed no dose response correlation: in HVs, 1 mild headache (5 mg/kg IV), 1 mild flushing (1.5 mg/kg SC), and 1 mild anemia (360 mg SC); in AD subjects: 1 mild headache/mild decreased appetite (1.5 mg/kg IV), 1 moderate dizziness (7.5 mg/kg IV), 1 mild dizziness (1.5 mg/kg SC), and 1 mild somnolence (PBO IV). There were no infusion reactions. No injection site reactions were seen in any of the 17 SC subjects.

To assess target engagement and the clinical PD effect of KPL-716 in subjects with AD after a single dose, the weekly average WI-NRS on Day 28 was compared between KPL-716 recipients at 7.5 mg/kg IV (n=10) and pooled PBO IV recipients (n=10). Baseline mean weekly average WINRS was balanced: 8.0 (KPL-716) vs. 8.2 (PBO); between Day 0 to Day 28, AD flares occurred in 2 KPL-716 recipients and 2 PBO recipients.

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Mean percentage change in weekly average WI-NRS was greater in KPL-716 recipients vs. PBO: -40.4% vs. -17.6%. A higher percentage of KPL-716 recipients demonstrated a \geq 4-point decrease in weekly average WI-NRS vs. PBO: 50% vs. 10%. The maximum decrease in WI-NRS was greater in KPL-716 recipients vs. PBO: \geq 8 points vs. 4 points, with a \geq 6-point decrease in 30% of KPL-716 recipients. Mean percentage change in Eczema Area and Severity Index (EASI) was greater in KPL-716 recipients vs. PBO: -42.3% vs. 25%. Concordant with the effect on pruritus, KPL-716 recipients reported improved sleep vs. PBO, as evidenced by a greater decrease in sleep-loss VAS: -59.5% vs. -2.3%.

Conclusions: These data represent the first demonstration of the safety and tolerability profile and the antipruritic effect of OSMR β inhibition and support further clinical development of KPL-716 in chronic pruritic indications.
