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): **April 22, 2020**

Kiniksa Pharmaceuticals, Ltd.
(Exact name of Registrant as Specified in Its Charter)

Bermuda	**001-730430**	**98-1327726**
(State or other jurisdiction of incorporation or organization)	(Commission File Number)	(I.R.S. Employer Identification No.)

Kiniksa Pharmaceuticals, Ltd.
Clarendon House 2 Church Street
Hamilton HM11, Bermuda (808) 451-3453
(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 or Former Address, 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))

Securities registered pursuant to Section 12(b) of the Act:

Title of each class	**Trading Symbol(s)**	**Name of each exchange on which registered**
Class A Common Shares $0.000273235 par value	KNSA	The Nasdaq Global Select Market

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 ☒

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. ☒

Item 7.01. Regulation FD Disclosure.

On April 22, 2020, Kiniksa Pharmaceuticals, Ltd. (the "Company") issued a press release announcing data from its Phase 2a clinical trial with Vixarelimab (KPL-716) in prurigo nodularis. A copy of the press release and a slide-deck containing data from the trial are furnished with this Current Report on Form 8-K as Exhibits 99.1 and 99.2, respectively.

The information contained in this Item 7.01 of this Current Report on Form 8-K and Exhibits 99.1 and 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.

Item 9.01. Financial Statements and Exhibits.

(d) Exhibits

Exhibit No.	**Description**
99.1	Vixarelimab (KPL-716) Phase 2a Data Press Release issued by Kiniksa Pharmaceuticals, Ltd. dated April 22, 2020
99.2	Kiniksa Pharmaceuticals, Ltd. Vixarelimab (KPL-716) Phase 2a Data Slide-Deck

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: April 22, 2020

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

Exhibit 99.1

Kiniksa Announces Phase 2 Clinical Trial of Vixarelimab (KPL-716) in Prurigo Nodularis Meets Primary Efficacy Endpoint

- *Statistically significant primary efficacy endpoint of reduction in weekly-average Worst-Itch Numeric Rating Scale (WI-NRS) at Week 8*
- *Statistically significant secondary efficacy endpoint of improvement in prurigo nodularis-investigator's global assessment (PN-IGA) 0/1 at Week 8*

HAMILTON, BERMUDA – April 22, 2020 – 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 announced data from the Phase 2a clinical trial in prurigo nodularis for vixarelimab (KPL-716), a fully-human monoclonal antibody that targets oncostatin M receptor beta (OSMRβ). The trial met its primary efficacy endpoint: the reduction in weekly-average WI-NRS from baseline at Week 8 was statistically significantly greater in patients who received vixarelimab versus those who received placebo. Additionally, a statistically significant percentage of vixarelimab recipients achieved a PN-IGA score of 0/1 at Week 8 compared to placebo recipients, and the majority of vixarelimab recipients showed a clinically meaningful greater-than-or-equal-to 4-point weekly-average WI-NRS reduction at Week 8.

The Phase 2a trial enrolled and treated 49 patients with moderate-to-severe prurigo nodularis (mean PN-IGA of 3.4) experiencing moderate-to-severe pruritus (mean WI-NRS score of 8.3). Patients were randomized 1:1 to receive a loading dose of vixarelimab 720 mg (n=23) or placebo (n=26) subcutaneous (SC) followed by vixarelimab 360 mg or placebo SC weekly. The primary efficacy endpoint was percent change versus baseline in weekly-average WI-NRS at Week 8 (using the last observation carried forward analysis).

- Least squares-mean change from baseline in weekly-average WI-NRS at Week 8 was -50.6% in vixarelimab recipients compared to -29.4% in placebo recipients (mean difference 21.1%; p=0.035).
- Median change from baseline in weekly-average WI-NRS at Week 8 was -69.8% in vixarelimab recipients compared to -36.1% in placebo recipients.
- 30.4% of vixarelimab recipients achieved a PN-IGA score of 0/1 at Week 8 compared to 7.7% of placebo recipients (p=0.032).
- 52.2% of vixarelimab recipients demonstrated a ≥ 4-point reduction in weekly-average WI-NRS at Week 8 compared to 30.8% of placebo recipients (p=0.109).

In this Phase 2a trial, vixarelimab was well-tolerated by all subjects and no dose-limiting adverse experiences were observed. There were no serious adverse events or atopic dermatitis flares.

“The data from the Phase 2a study showed that vixarelimab had a clinically meaningful effect in these patients with prurigo nodularis,” said John F. Paolini, MD, PhD, Chief Medical Officer of Kiniksa. “The potential impact and differentiation of the OSMRβ mechanism was demonstrated: in addition to the nearly 70% reduction in the median weekly-average WI-NRS at Week 8, a disease severity benefit was seen, with approximately a third of vixarelimab-treated patients attaining a clear or almost clear lesion score by Week 8. Vixarelimab has demonstrated encouraging results in both pruritus and nodule response and has the potential to positively impact the lives of patients with prurigo nodularis.”

The data presentation from the Phase 2a trial of vixarelimab in prurigo nodularis, including images of nodule response, is available through the Investors and Media section of Kiniksa’s website (www.investors.kiniksa.com).

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’s clinical-stage product candidates, rilonacept, mavrilimumab, vixarelimab and KPL-404, are based on strong biologic rationale or validated mechanisms, target underserved conditions, and offer the potential for differentiation. These pipeline assets are designed to modulate immunological signaling pathways that are implicated across a spectrum of diseases. For more information, please visit www.kiniksa.com.

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

About Vixarelimab Phase 2a Trial in Prurigo Nodularis
The Phase 2a trial was a randomized, double-blind, placebo-controlled study designed to investigate the efficacy, safety, tolerability, and pharmacokinetics of vixarelimab in reducing pruritus in subjects with prurigo nodularis. The trial enrolled patients with moderate-to-severe prurigo nodularis experiencing moderate-to-severe pruritus (WI-NRS ≥ 7 at the screening visit and a mean weekly WI-NRS of ≥ 5 for each of the two consecutive weeks immediately prior to randomization). Patients were required to stop antihistamines and topical treatments, including corticosteroids, for at least two weeks prior to dosing. Prurigo nodularis treatments, other than study drug, were not allowed except for rescue. For more information, refer to ClinicalTrials.gov Identifier: NCT03816891.

Forward-Looking Statements
The information contained in this press release 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 press release that do not relate to matters of historical fact should be considered forward-looking statements, including without limitation, statements regarding the potential impact and differentiation of the OSMRβ mechanism; the potential for vixarelimab (KPL-716) to positively impact the lives of patients with prurigo nodularis; and the potential for all of our clinical stage product candidates to offer differentiation.

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: the potential for changes between final or a broader set of data and any "top-line," interim and preliminary data we announce; impact of additional data from us or other companies; the potential inability to replicate in later clinical trials positive results from our Phase 2a clinical trial with vixarelimab in patients with prurigo nodularis; the potential for undesirable side effects to be caused by vixarelimab; our reliance on third parties to conduct clinical trials for vixarelimab; the impact of the COVID-19 pandemic and measures taken in response to the pandemic; changes in our operating plan and funding requirements; existing or new competition; and our ability to attract and retain qualified personnel.

These and other important factors discussed under the caption "Risk Factors" in our Annual Report on Form 10-K filed with the Securities and Exchange Commission ("SEC") on March 5, 2020 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 press release. Any such forward-looking statements represent management's estimates as of the date of this press release. 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 press release.

Every Second Counts!™

Kiniksa Investor and Media Contact
Mark Ragosa
(781) 430-8779
mragosa@kiniksa.com

Exhibit 99.2


KINIKSA
Every Second Counts!™
Vixarelimab (KPL-716) Phase 2a
Prurigo Nodularis Data
April 2020

Summary of Vixarelimab Phase 2a Study Prurigo Nodularis

Enrolled and treated 49 patients with moderate-to-severe prurigo nodularis (mean PN- IGA of 3.4) experiencing moderate-to-severe pruritus (mean WI-NRS score of 8.3)

- Randomized 1:1 to receive a loading dose of vixarelimab 720 mg (n=23) or placebo (n=26) subcutaneous (SC) followed by vixarelimab 360 mg or placebo SC weekly
- Data includes 49 subjects through the 8-week treatment period

Primary Efficacy Endpoint: percent change versus baseline in weekly-average WI-NRS at Week 8 (using the last observation carried forward analysis)

Topline Observations:

- Least squares-mean change from baseline in weekly-average WI-NRS at Week 8 was -50.6% in vixarelimab recipients compared to -29.4% in placebo recipients (mean difference 21.1%; p=0.035)
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WI-NRS = Worst-Itch Numeric Rating Scale
PN-IGA = prurigo nodularis-investigator's global assessment

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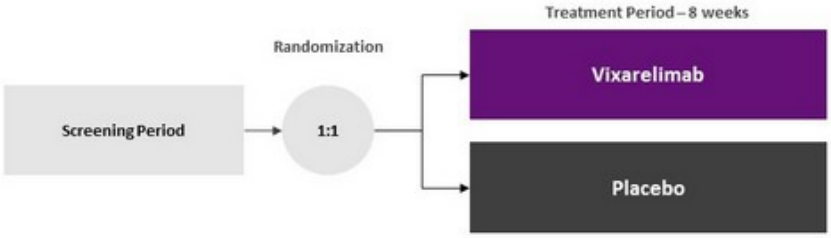
Vixarelimab Phase 2a Trial in Prurigo Nodularis

Phase 2a Proof-of-Concept

Objective: Assess pruritus reduction

Dose: 720 mg SC loading dose --> 360 mg single SC QW thereafter

Primary Efficacy Endpoint : % change from baseline in weekly average Worst Itch-Numeric Rating Scale (WI-NRS)



Inclusion Criteria

- Male or female aged 18 to 75 years, inclusive, at the time of consent
- Have a physician-documented diagnosis of prurigo nodularis that is confirmed by review of medical photography during the Screening Period. Duration of prurigo nodularis (since the time of first PN nodule) must be at least 6 months from the time of first PN nodule to Day 1, as affirmed by the subject
- Have at least 10 nodules of approximately 0.5 to 2 cm at the Screening Visit and Day 1. The nodules must be pruritic and present on at least 2 different anatomical locations (not be localized), involve the extremities, with extensor extremity involvement greater than the flexor extremity involvement. Nodules on the head (face and scalp) are not counted as an anatomical location for eligibility criteria. There must be normal appearing skin present in between nodules with the exception of atopic dermatitis. Each arm, each leg, and trunk are considered different anatomical locations
- Subject has moderate to severe pruritus, defined as WI-NRS ≥ 7 at the Screening Visit and a mean weekly WI-NRS ≥ 5 for each of the 2 consecutive weeks immediately prior to randomization
- Patients were required to stop antihistamines and topical treatments, including corticosteroids, for at least two weeks prior to dosing
- Prurigo nodularis treatments, other than study drug, were not allowed except for rescue

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Baseline Characteristics

General Characteristics*	Vixarelimab (n=23)	Placebo (n=26)	Total (n=49)
Age (Mean Years)	52	64	58
Sex (Male/Female)	10/13	10/16	20/29
Race			
White (n)	65.2% (15)	80.8% (21)	73.5% (36)
Black or African American (n)	21.7% (5)	11.5% (3)	16.3% (8)
Asian (n)	8.7% (2)	0	4.1% (2)
American Indian or Alaska Native (n)	0	3.8% (1)	2.0% (1)
Multiple (n)	4.3% (1)	0	2.0% (1)
Other (n)	0	3.8% (1)	2.0% (1)

*mITT Analysis Set

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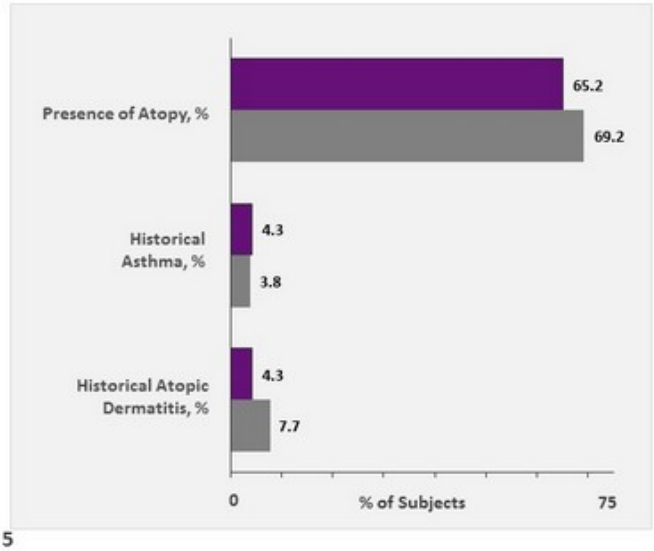
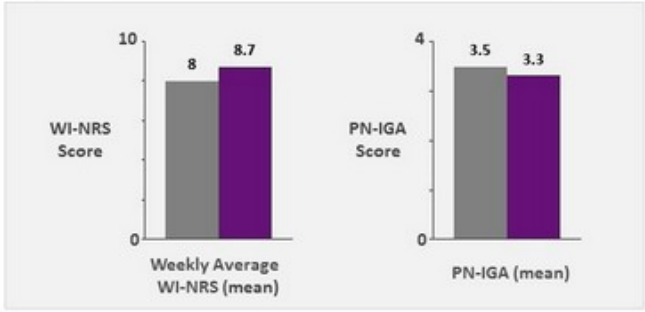
Baseline Characteristics

Clinical Findings at Baseline: History of Atopy



Clinical Findings at Baseline: WI-NRS & PN-IGA



Vixarelimab
Placebo

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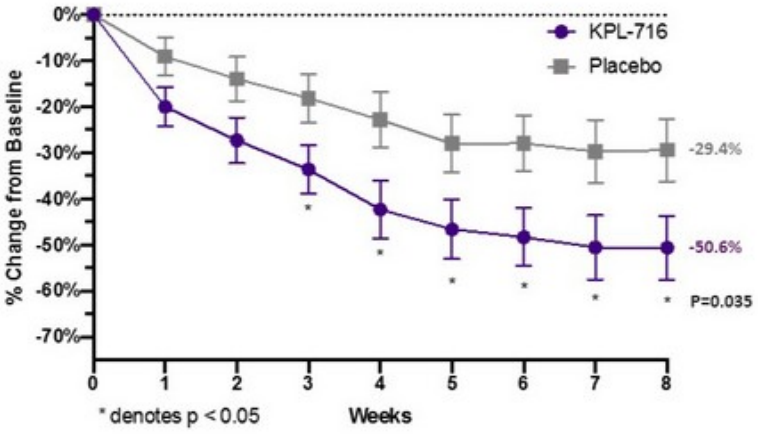
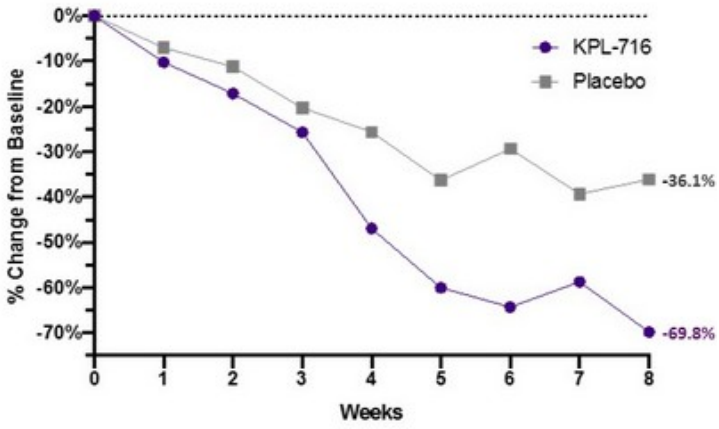
Vixarelimab (KPL-716) Phase 2 Study Showed a Statistically Significant Reduction in Mean Weekly-Average WI-NRS Versus Placebo

Median change from baseline in weekly-average WI-NRS at Week 8 was -69.8%

LS-Mean % Change in Weekly Average WI-NRS



Median % Change in Weekly Average WI-NRS



WI-NRS = Worst-Itch Numeric Rating Scale
LS = least squares

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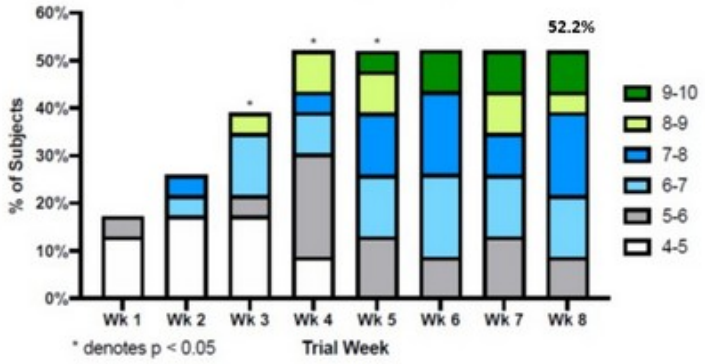
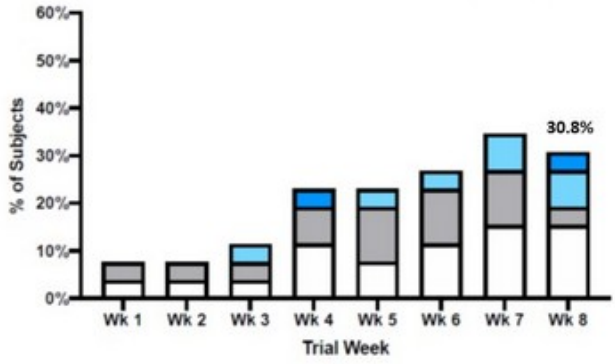
The Majority of Vixarelimab (KPL-716) Recipients Showed a Clinically Meaningful ≥4-Point WI-NRS Reduction

% of KPL-716 Subjects with a Clinically Meaningful Response in WI-NRS



% of Placebo Subjects with a Clinically Meaningful Response in WI-NRS



WI-NRS = Worst-Itch Numeric Rating Scale

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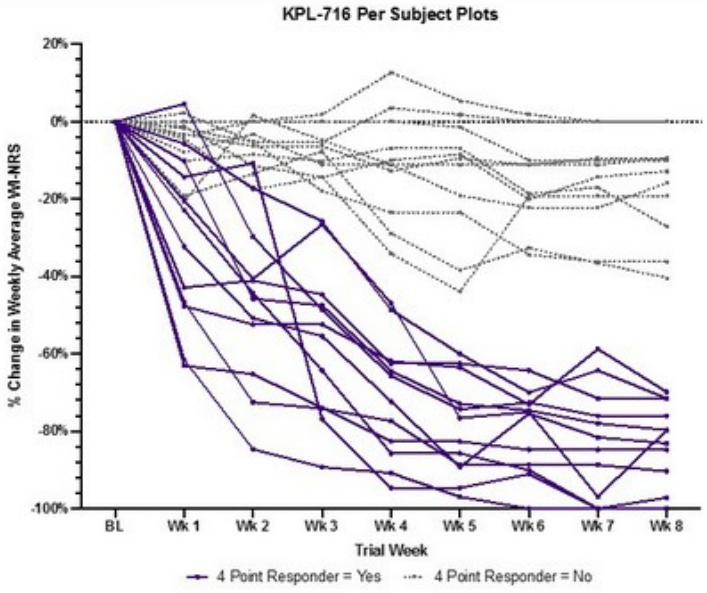
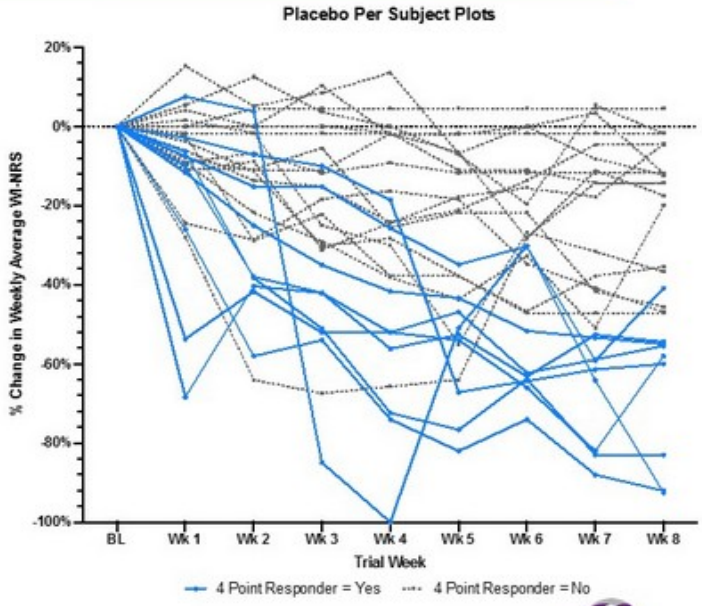
The Majority of Vixarelimab (KPL-716) Recipients Showed a Clinically Meaningful ≥4-Point WI-NRS Reduction





WI-NRS = Worst-Itch Numeric Rating Scale

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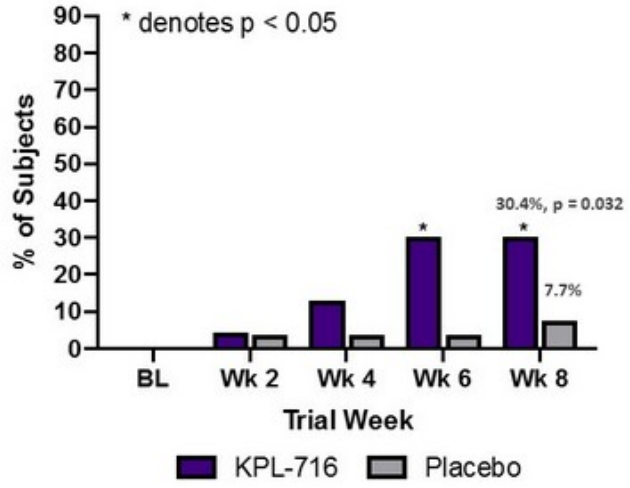
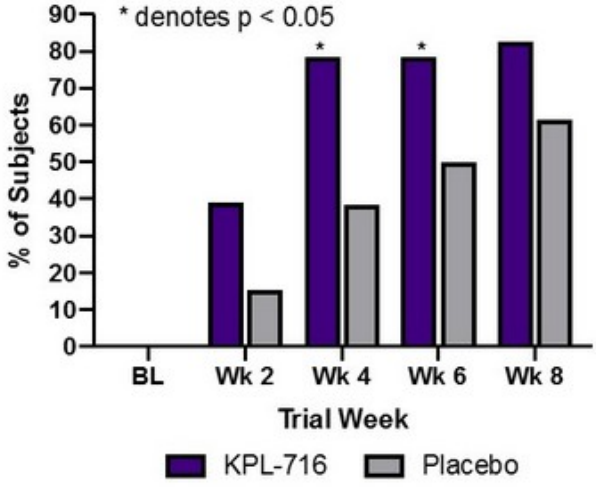
Disease Severity Response: Significantly More Vixarelimab (KPL-716) Recipients Attained A Clear/Almost Clear Lesion Score by Week 8 Versus Placebo

PN-IGA Score of 0 or 1 & a ≥2 Point Reduction



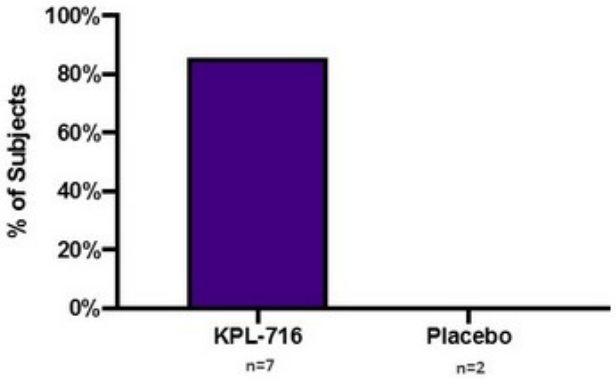
≥1 Point Change in PN-IGA



PN-IGA = prurigo nodularis-investigator's global assessment

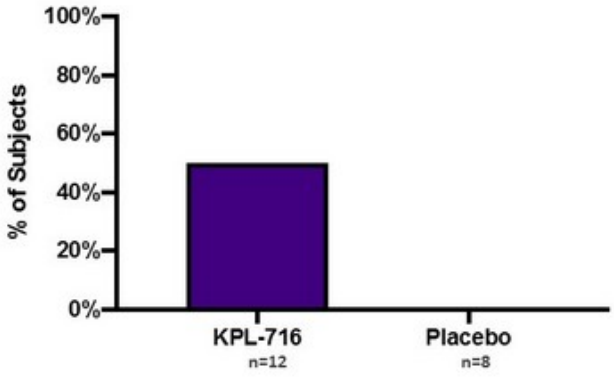
Concordant Effect of Vixarelimab (KPL-716) on PN-IGA and Pruritus

% of IGA 0-1 Subjects with ≥4 Point Change in WI-NRS



85.7% of the subjects who achieved 0-1 on the PN-IGA scale were also 4-point responders on WI-NRS vs. none for placebo

% of Subjects with ≥4 Point Change in WI-NRS and an IGA of 0-1



50% of the subjects who had a clinically meaningful reduction in itch by week 8 also had an PN-IGA score of 0-1 vs. none for placebo

WI-NRS = Worst-Itch Numeric Rating Scale
PN-IGA = prurigo nodularis-investigator's global assessment

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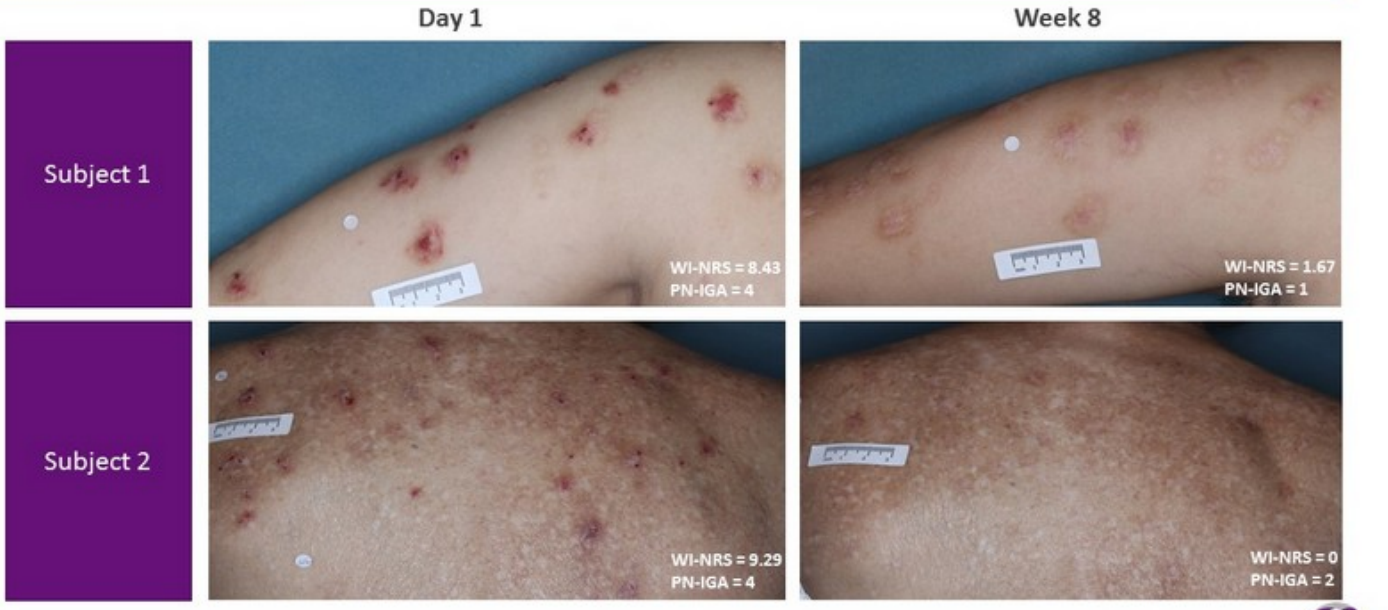
Representative Images of Nodule Resolution at Week 8 in Two Vixarelimab-Treated Subjects



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Vixarelimab was Well-Tolerated in Prurigo Nodularis Phase 2a Study

	Vixarelimab (n=23)	Placebo (n=26)
Any AE (n)	82.6% (19)	65.4% (17)
TEAE (n)	82.6% (19)	65.4% (17)
Drug-Related TEAE (n)	39.1% (9)	30.8% (8)
Serious TEAE	0	0
Drug-Related Serious TEAE	0	0
TEAE Leading to Treatment Discontinuation	0	0
Drug-Related TEAE Leading to Treatment Discontinuation	0	0
Serious TEAE Leading to Treatment Discontinuation	0	0
Drug-Related Serious TEAE Leading to Treatment Discontinuation	0	0
TEAE Leading to Death	0	0

AE = adverse event
TEAE = treatment emergent adverse event

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Vixarelimab was Well-Tolerated in Prurigo Nodularis Phase 2a Study

System Organ Class Preferred Term	Vixarelimab (n=23)	Placebo (n=26)
Infections and Infestations (n)	30.4% (7)	46.2% (12)
Upper Respiratory Tract Infection (n)	17.4% (4)	3.8% (1)
Nasopharyngitis (n)	4.3% (1)	7.7% (2)
Gastroenteritis Viral (n)	4.3% (1)	0
Influenza (n)	4.3% (1)	0
Postoperative Wound Infection (n)	4.3% (1)	0
Subcutaneous Abscess (n)	4.3% (1)	0
Urinary Tract Infection (n)	0	11.5% (3)
Bronchitis (n)	0	3.8% (1)
Cellulitis (n)	0	3.8% (1)
Eczema Impetiginous (n)	0	3.8% (1)
Herpes Simplex (n)	0	3.8% (1)
Otis Media (n)	0	3.8% (1)
Skin Infection (n)	0	3.8% (1)
Tooth Abscess (n)	0	3.8% (1)

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Vixarelimab was Well-Tolerated in Prurigo Nodularis Phase 2a Study

System Organ Class Preferred Term	Vixarelimab (n=23)	Placebo (n=26)
Skin and Subcutaneous Tissue Disorders	26.1% (6)	15.4% (4)
Eczema Nummular	4.3% (1)	3.8% (1)
Pruritus	4.3% (1)	3.8% (1)
Dermatitis Allergic	4.3% (1)	0
Idiopathic Angioedema	4.3% (1)	0
Night Sweats	4.3% (1)	0
Urticaria	4.3% (1)	0
Skin Burning Sensation	0	7.7% (2)
Neurodermatitis	0	3.8% (1)

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Summary of Vixarelimab Phase 2a Study Prurigo Nodularis

Enrolled and treated 49 patients with moderate-to-severe prurigo nodularis (mean PN- IGA of 3.4) experiencing moderate-to-severe pruritus (mean WI-NRS score of 8.3)

- Randomized 1:1 to receive a loading dose of vixarelimab 720 mg (n=23) or placebo (n=26) subcutaneous (SC) followed by vixarelimab 360 mg or placebo SC weekly
- Data includes 49 subjects through the 8-week treatment period

Primary Efficacy Endpoint: percent change versus baseline in weekly-average WI-NRS at Week 8 (using the last observation carried forward analysis)

Topline Observations:

- Least squares-mean change from baseline in weekly-average WI-NRS at Week 8 was -50.6% in vixarelimab recipients compared to -29.4% in placebo recipients (mean difference 21.1%; p = 0.035)
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PN-IGA = prurigo nodularis-investigator's global assessment

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