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): May 29, 2019

CARA THERAPEUTICS, INC.
(Exact name of registrant as specified in its charter)

Delaware	**001-36279**	**75-3175693**
(State or other jurisdiction of incorporation)	**(Commission File Number)**	**(IRS Employer Identification No.)**

4 Stamford Plaza **107 Elm Street, 9th Floor** **Stamford, Connecticut**	**06902**
(Address of principal executive offices)	**(Zip Code)**

Registrant's telephone number, including area code: (203) 406-3700

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 (*see* General Instruction A.2.):

☐ 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
Common stock, par value $0.001 per share	**CARA**	**The Nasdaq Stock Market LLC**

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 May 29, 2019, Cara Therapeutics, Inc. (the "Company") issued a press release announcing top-line data from its KALM-1 trial, a multicenter, randomized, double-blind, placebo controlled Phase 3 trial in the United States, evaluating the safety and efficacy of KORSUVA injection in hemodialysis patients with moderate-to-severe pruritus. The Company will hold a conference call to discuss the results at 8:30 a.m. EDT on May 29, 2019. A copy of the press release and the presentation to be discussed on the conference call are furnished as Exhibit 99.1 and Exhibit 99.2, respectively, to this Current Report on Form 8-K and incorporated herein by reference.

The information furnished under this Item 7.01, including 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, or subject to the liabilities of that section. The information shall not be deemed incorporated by reference into any other filing with the Securities and Exchange Commission made by the Company, regardless of any general incorporation language in such filing.

Item 8.01 Other Information.

On May 29, 2019, the Company issued a press release announcing top-line data from its KALM-1 trial, a multicenter, randomized, double-blind, placebo controlled Phase 3 trial in the United States, evaluating the safety and efficacy of KORSUVA injection in hemodialysis patients with moderate-to-severe pruritus.

KALM-1 Phase 3 Trial Design

The KALM-1 Phase 3 U.S. trial is a multicenter, randomized, double-blind, placebo-controlled 12-week treatment trial with a 52-week open label extension phase that is designed to evaluate the safety and efficacy of 0.5 mcg/kg KORSUVA (CR845/difelikefalin) injection in 350 hemodialysis patients with moderate-to-severe pruritus.

The primary efficacy endpoint is the proportion of patients achieving at least a three-point improvement from baseline in the weekly mean of the daily 24-hour Worst Itch Numeric Rating Scale (WI-NRS) score at week 12.

Secondary endpoints include assessment of itch-related quality of life changes measured using the validated self-assessment 5-D itch and Skindex-10 scales, as well as the proportion of patients achieving ³ four-point improvement from baseline in weekly mean of the daily 24-hour WI-NRS score at week 12.

KALM-1 Efficacy Data:

- *Primary Endpoint*: The proportion of patients receiving 0.5mcg/kg of KORSUVA injection achieving a ³ three-point improvement from baseline in the weekly mean of the daily 24-hour WI-NRS score at week 12 was 51%, compared to 28% for patients receiving placebo (p= 0.000019).
- *Secondary Endpoints*:
  - *4-point Improvement from baseline in 24-hour WI-NRS score*. The proportion of patients receiving 0.5mcg/kg of KORSUVA injection achieving a ³ four-point improvement from baseline in the weekly mean of the daily 24 hour WI-NRS score at week 12 was 39%, compared to 18% for patients receiving placebo (p= 0.000032).
  - *Itch-Related Quality of Life Measures*:
    - Patients receiving KORSUVA injection experienced a 43% improvement in the average total Skindex-10 score at week 12, compared to patients receiving placebo (p= 0.0004).
    - Patients receiving KORSUVA injection experienced a 35% improvement in the average total 5-D Itch score at week 12, compared to patients receiving placebo (p= 0.0009).

KALM-1 Safety and Tolerability:

KORSUVA was generally well-tolerated with a safety profile consistent with that seen in earlier KORSUVA clinical trials. Overall, the incidence of adverse events ("AEs") and serious AEs were similar across both KORSUVA and placebo groups. The most common treatment emergent AEs reported in ³ 5% patients were diarrhea (9.5% KORSUVA vs. 3.7% placebo), dizziness (6.9% KORSUVA vs. 1.1% placebo), nasopharyngitis (KORSUVA 5.3% vs. 3.2% placebo) and vomiting (5.3% KORSUVA vs. 3.2% placebo).

Item 9.01 Financial Statements and Exhibits.

(d) Exhibits

Exhibit No.	
99.1	Press release dated May 29, 2019.
99.2	Presentation dated May 29, 2019.

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.

CARA THERAPEUTICS, INC.

By: /s/ Mani Mohindru
Mani Mohindru, Ph.D.
Chief Financial Officer
(Principal Financial and Accounting Officer)

Date: May 29, 2019

Cara Therapeutics Announces Positive Results From KALM-1 Pivotal Phase 3 Trial of KORSUVA™ Injection in Hemodialysis Patients with Pruritus

- ***Statistically significant improvement in primary endpoint of proportion of patients with three point or greater reduction in mean worst itching intensity NRS score vs. placebo (p=0.000019) –***

- ***Statistically significant improvement in key secondary endpoint of proportion of patients with four point or greater reduction in mean worst itching intensity NRS score vs. placebo (p=0.000032) –***

- ***KORSUVA Injection well-tolerated through 12 weeks of treatment*** -

- ***Company to host conference call today at 8:30 a.m. ET*** -

STAMFORD, Conn., May 29, 2019 – Cara Therapeutics, Inc. (Nasdaq:CARA), a biopharmaceutical company focused on developing and commercializing new chemical entities with a primary focus on the treatment of pruritus by selectively targeting peripheral kappa opioid receptors, today announced positive topline data from the KALM-1 pivotal Phase 3 trial of KORSUVA™ (CR845/difelikefalin) Injection in hemodialysis patients with moderate-to-severe chronic kidney disease-associated pruritus (CKD-aP).

"We are extremely pleased with the robust topline results from our first pivotal Phase 3 trial of KORSUVA Injection and are particularly encouraged by the early anti-pruritic response with KORSUVA Injection, which resulted in statistically significant separation from placebo after only one week of treatment and a sustained significant benefit through 12 weeks," said Derek Chalmers, Ph.D., D.Sc., President and Chief Executive Officer of Cara Therapeutics. "We look forward to reporting topline data from our second global Phase 3 trial, KALM-2, in the second half of this year and, assuming positive results, moving towards an NDA submission as quickly as possible thereafter."

CKD-aP is an intractable systemic itch condition that occurs with high frequency and intensity in patients undergoing hemodialysis and peritoneal dialysis. Multiple studies estimate that at least 40 percent of patients with end-stage renal disease suffer from pruritus. The U.S. Food and Drug Administration (FDA) has granted Breakthrough Therapy designation to KORSUVA Injection for this indication.

“Itching is a significant problem for many of our hemodialysis patients and there is an unmet need for an effective treatment. I am impressed by the clinically meaningful efficacy demonstrated in this study,” said Steven Fishbane, M.D., Chief, Division of Kidney Disease and Hypertension, Northwell Health, Professor of Medicine at Hofstra/Northwell and a KALM-1 clinical investigator. “Relative to the favorable safety data, these results suggest that, if approved, this can be an important drug that could help many of our patients.”

KALM-1 Efficacy Data:

- *Primary Endpoint*: The proportion of patients on 0.5 mcg/kg of KORSUVA Injection achieving a three-point or greater improvement from baseline in the weekly mean of the daily 24 hour Worst Itching Intensity Numeric Rating Scale (WI-NRS) score at week 12 was 51% vs. 28% for patients on placebo (p= 0.000019)
- *Secondary Endpoints*:
  - The proportion of patients on 0.5 mcg/kg of KORSUVA Injection achieving a four-point or greater improvement from baseline in the weekly mean of the daily 24 hour WI-NRS score at week 12 was 39% vs. 18% for patients on placebo (p= 0.000032)
  - *Itch-Related Quality of Life Measures*: The impact of KORSUVA Injection on itch-related quality of life measures associated with CKD-aP was measured using validated self-assessment Skindex-10 and 5-D itch scales:
    - Patients on KORSUVA Injection experienced a 43% improvement in the average total Skindex-10 score at week 12 vs. patients on placebo (p= 0.0004)
    - Patients on KORSUVA Injection experienced a 35% improvement in the average total 5-D Itch score at week 12 vs. patients on placebo (p= 0.0009)

KALM-1 Safety and Tolerability:

KORSUVA was generally well-tolerated with a safety profile consistent with that seen in earlier KORSUVA clinical trials. Overall, the incidence of adverse events (AEs) and serious AEs were similar across both KORSUVA and placebo groups. The most common treatment emergent AEs reported in [3] 5% of patients were diarrhea (9.5% KORSUVA vs 3.7% placebo), dizziness (6.9% KORSUVA vs 1.1% placebo), nasopharyngitis (KORSUVA 5.3% vs 3.2% placebo) and vomiting (5.3% KORSUVA vs 3.2% placebo).

Conference Call

Cara management will host a conference call today at 8:30 a.m. ET to discuss the results of the study.

To participate in the conference call, please dial (855) 445-2816 (domestic) or (484) 756-4300 (international) and refer to conference ID 2987032. A live webcast of the call can be accessed under “Events & Presentations” in the News & Investors section of the Company’s website at www.CaraTherapeutics.com.

An archived webcast recording will be available on the Cara website beginning approximately two hours after the call.

KALM-1 Phase 3 Trial Design

The Phase 3 U.S. study is a multicenter, randomized, double-blind, placebo-controlled 12-week treatment trial with a 52-week open label extension phase that is designed to evaluate the safety and efficacy of 0.5 mcg/kg KORSUVA (CR845/difelikefalin) Injection in 350 hemodialysis patients with moderate-to-severe pruritus.

The primary efficacy endpoint is the proportion of patients achieving at least a three-point improvement from baseline in the weekly mean of the daily 24-hour WI-NRS score at week 12.

Secondary endpoints include assessment of itch-related quality of life changes measured using the validated self-assessment 5-D itch and Skindex-10 scales, as well as the proportion of patients achieving at least a four-point improvement from baseline in weekly mean of the daily 24-hour WI-NRS score at week 12.

About CKD-aP

CKD-aP is an intractable systemic itch condition that occurs with high frequency and intensity in patients with chronic kidney disease undergoing hemodialysis and peritoneal dialysis. Pruritus has also been reported in patients with stage III-V CKD who are not on dialysis. Aggregate, longitudinal, multi-country studies estimate the weighted prevalence of CKD-aP to be approximately 40 percent in patients with end-stage renal disease (ESRD), with approximately 25 percent of patients reporting severe pruritus. The majority of dialysis patients (approximately 60-70 percent) report pruritus, with 30 to 40 percent reporting moderate or severe pruritus.[1,2] Recent data from the ITCH National Registry Study showed that among those with pruritus, approximately 59 percent experienced symptoms daily or nearly daily for more than a year. Given its association with CKD/ESRD, most afflicted patients will continue to have symptoms for months or years, with currently employed antipruritic treatments, such as antihistamines and corticosteroids, unable to provide consistent, adequate relief. Moderate-to-severe chronic pruritus has repeatedly been shown to directly decrease quality of life, contribute to symptoms

that impair quality of life (such as poor sleep quality), and is associated with depression.[3] CKD-aP is also an independent predictor of mortality among hemodialysis patients, mainly related to increased risk of inflammation and infections.

References:

1. Pisoni RL, et al. Pruritus in haemodialysis patients: international results from the Dialysis Outcomes and Practice Patterns Study (DOPPS). Nephrol Dial Transplant. 2006; 21:3495-3505.
2. Ramakrishnan K, et al. Clinical characteristics and outcomes of end-stage renal disease patients with self-reported pruritus symptoms. International Journal of Nephrology and Renovascular Disease. 2014; 7: 1-12.
3. Mathur VS, et al. A longitudinal study of Uremic Pruritus in hemodialysis patients. Clin J Am Soc Nephrol. 2010; 5(8):1410-1419.

About Cara Therapeutics

Cara Therapeutics is a clinical-stage biopharmaceutical company focused on developing and commercializing new chemical entities designed to alleviate pruritus by selectively targeting peripheral kappa opioid receptors (KORs). Cara is developing a novel and proprietary class of product candidates, led by KORSUVA™ (CR845/difelikefalin), a first-in-class KOR agonist that targets the body's peripheral nervous system, as well as certain immune cells. In a Phase 3 trial and Phase 2 trials, KORSUVA injection has demonstrated statistically significant reductions in itch intensity and concomitant improvement in quality of life measures in hemodialysis patients with moderate-to-severe chronic kidney disease-associated pruritus (CKD-aP), and is currently being investigated in Phase 3 trials in hemodialysis patients with CKD-aP.

The FDA has conditionally accepted KORSUVA™ as the trade name for difelikefalin injection. CR845/difelikefalin is an investigational drug product and its safety and efficacy have not been fully evaluated by any regulatory authority.

Forward-looking Statements

Statements contained in this press release regarding matters that are not historical facts are "forward-looking statements" within the meaning of the Private Securities Litigation Reform Act of 1995. Examples of these forward-looking statements include statements concerning plans, strategies and expectations for the future, including the potential results of ongoing and planned clinical trials, future regulatory submissions; the size of the potential markets that are potentially addressable for the Company's product candidates, including the pruritus market, the potential for KORSUVA Injection to be a therapeutic option for CKD-aP, and the expected timing for announcement of the results of other ongoing clinical trials. Because such statements are subject to risks and uncertainties, actual results may differ materially from those expressed or

implied by such forward-looking statements. Risks are described more fully in Cara's filings with the Securities and Exchange Commission, including the "Risk Factors" section of Cara's Annual Report on Form 10-K for the year ended December 31, 2018 and its other documents subsequently filed with or furnished to the Securities and Exchange Commission. All forward-looking statements contained in this press release speak only as of the date on which they were made. Except to the extent required by law, Cara undertakes no obligation to update such statements to reflect events that occur or circumstances that exist after the date on which they were made.

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KORSUVA™ Injection
KALM-1 Phase 3 Pivotal Topline Results

A Multicenter, Randomized, 12-Week Double-Blind, Placebo-Controlled U.S. Study to Evaluate the Safety and Efficacy of Intravenous Dose of CR845 (KORSUVA™ Injection, 0.5 mcg/kg) In Patients Undergoing Hemodialysis With Moderate-to-Severe Pruritus

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Forward-Looking Statements

This presentation contains certain 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 the words “anticipate,” “believe,” “continue,” “estimate,” “expect,” “objective,” “ongoing,” “plan,” “propose,” “potential,” “projected”, or “up-coming” and/or the negative of these terms, or other comparable terminology intended to identify statements about the future. Examples of these forward-looking statements in this presentation include, among other things, statements concerning plans, strategies and expectations for the future, including statements regarding the expected timing of our planned clinical trials and the potential results of ongoing and planned clinical trials.

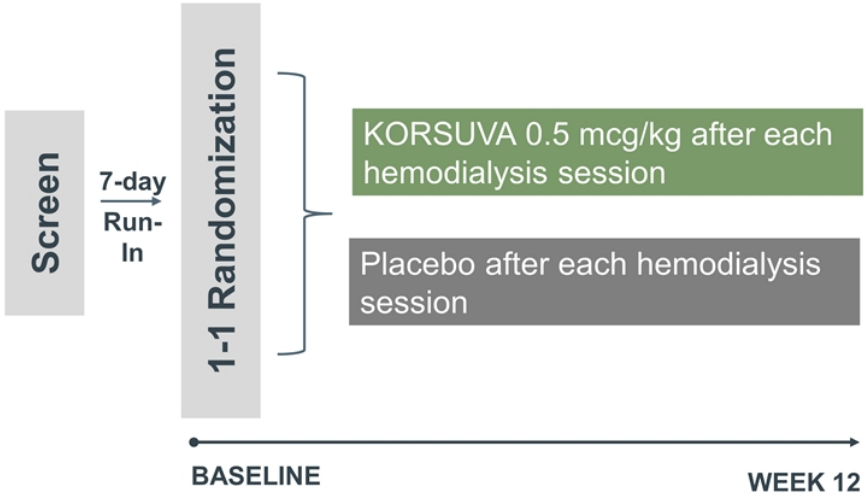
These statements involve known and unknown risks, uncertainties and other factors that may cause our actual results, levels of activity, performance or achievements to be materially different from the information expressed or implied by these forward-looking statements. Although we believe that we have a reasonable basis for each forward-looking statement contained in this presentation, we caution you that these statements are based on a combination of facts and factors currently known by us and our expectations of the future, about which we cannot be certain. Factors that may cause actual results to differ materially from any future results expressed or implied by any forward-looking statements include the risks described in the “Risk Factors” section of the Company’s Annual Report on Form 10-K for the year ended December 31, 2018, as well as those set forth from time to time in the Company’s other SEC filings, available at http://www.sec.gov. Any forward-looking statements speak only as of the date of this presentation.

The Company undertakes no obligation to publicly update any forward-looking statements, whether as a result of new information, future events or otherwise except as required by law.

Executive Summary

- KALM-1 Phase 3 pivotal study of KORSUVA™ Injection met primary and all secondary endpoints for the treatment of moderate-to-severe pruritus associated with chronic kidney disease in subjects undergoing hemodialysis
- KORSUVA™ Injection was generally well tolerated with the safety profile consistent with prior studies at the 0.5 mcg/kg dose
- Breakthrough designation in the US for this indication

KALM-1 Phase 3 Pivotal Study Design



52 Week Open-Label Extension Ongoing

Endpoints: Week 12

Primary

- Proportion of subjects achieving ≥3 point improvement from baseline in weekly mean of daily worst itching intensity NRS (WI-NRS)

Secondary

- Proportion of subjects achieving ≥4 point improvement from baseline in weekly mean of daily WI-NRS
- Change from baseline in itch-related Quality of Life as measured by 5-D Itch and Skindex-10 questionnaires

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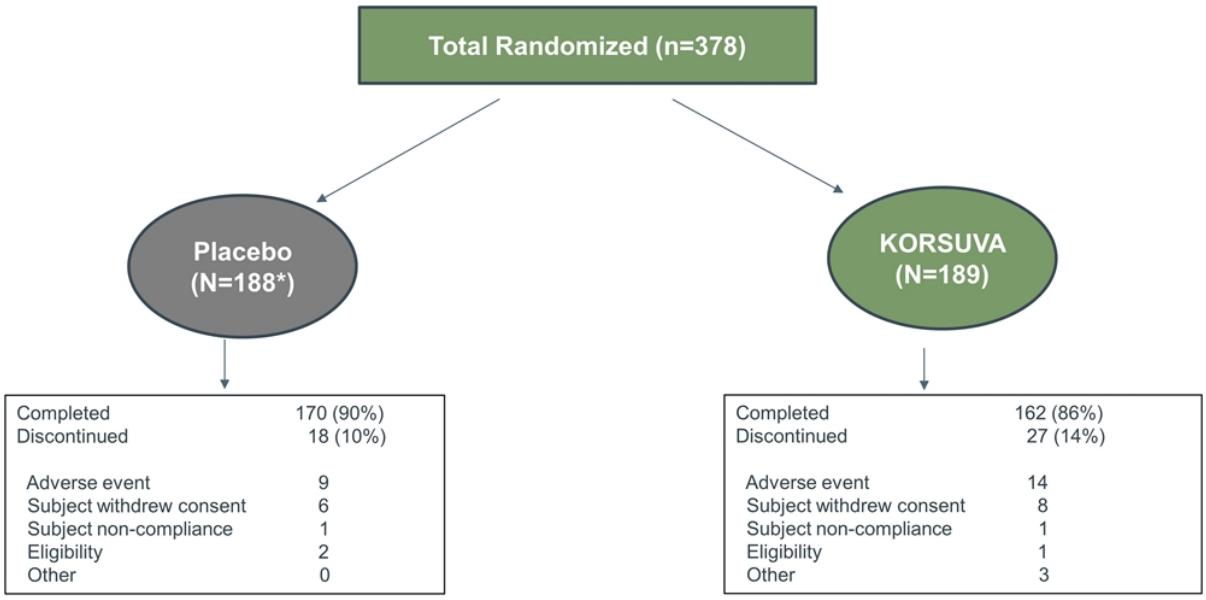
KALM-1: Disposition in Double-blind Treatment Period



*1 subject was randomized to Placebo but did not receive study drug

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KALM-1: Key Baseline Disease Characteristics

Baseline Characteristic Mean (SD) or %	Placebo N = 188	KORSUVA N = 189
Years Undergoing Hemodialysis,	4.7 (4.22)	4.4 (3.98)
Years of Pruritus	3.5 (3.37)	3.2 (3.24)
Use of Anti-Itch Medication	41.5 %	38.1 %
Baseline Worst Itching Intensity NRS	7.3 (1.61)	7.1 (1.44)
Baseline 5-D Itch Total Score	17.9 (3.47)	16.9 (3.47)
Baseline Skindex-10 Total Score	38.3 (15.40)	36.2 (14.36)

NRS: Numeric Rating Scale (0 to 10) where 0 = no itch and 10 = worst itching imaginable
5-D Itch score ranges from 0 to 25 (lower scores indicate better QoL and reduced itch symptoms)
Skindex-10 scale ranges from 0 to 60 (lower scores indicate better QoL)

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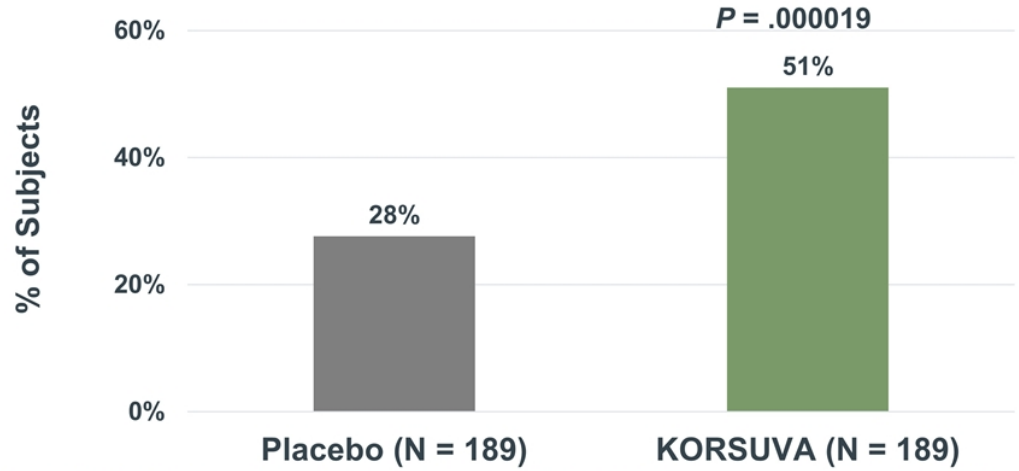
Primary Endpoint: ≥3 point improvement WI-NRS (Wk 12)

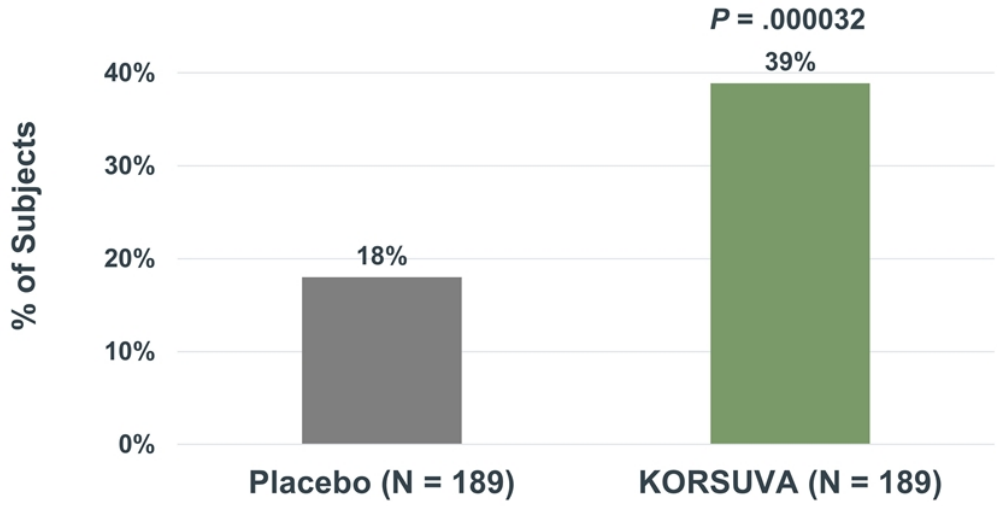
KORSUVA subjects >2.5 times more likely to experience ≥3 point improvement



Estimated percentage & P-value based on a logistic regression model with terms for treatment group, baseline WI-NRS score, and strata
Missing data imputed using multiple imputation (MI) under missing at random (MAR) assumption
Odds Ratio: 2.72

Secondary: ≥4 point improvement WI-NRS (Wk 12)

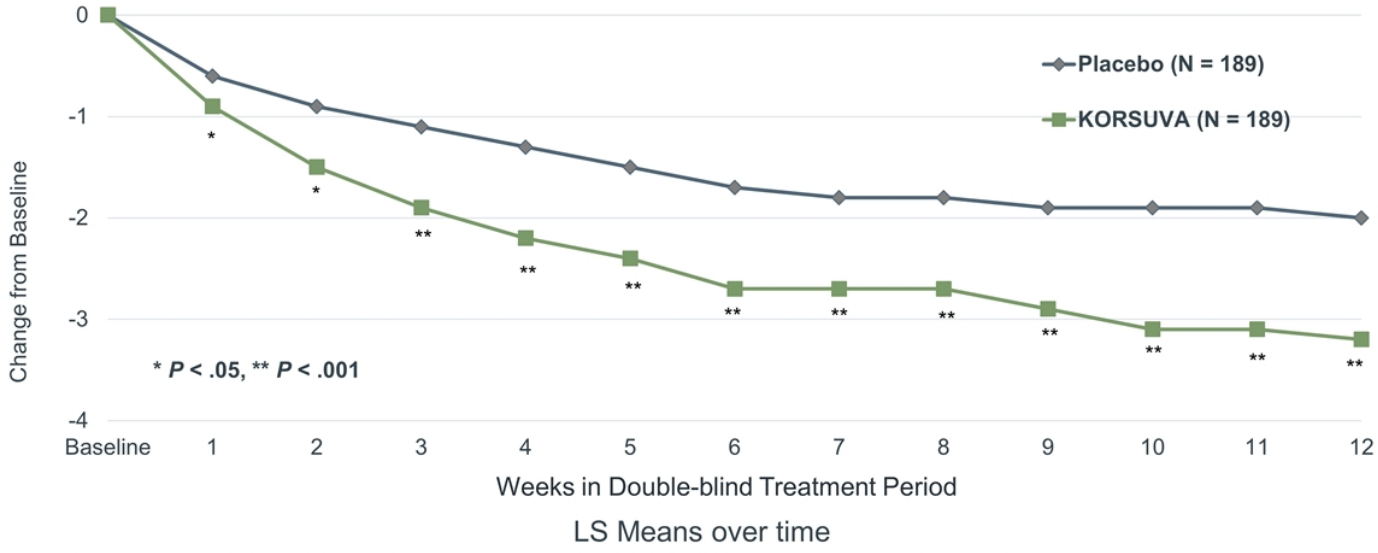
KORSUVA subjects ~3 times more likely to experience ≥4 point improvement



Estimated percentage & P-value based on a logistic regression model with terms for treatment group, baseline WI-NRS score, and strata
Missing data imputed using multiple imputation MI) under missing at random (MAR) assumption
Odds Ratio: 2.9

KALM-1 Change in Worst Itching Intensity NRS Over Time

Significant differences in WI-NRS Change between KORSUVA and Placebo Starting at Week 1



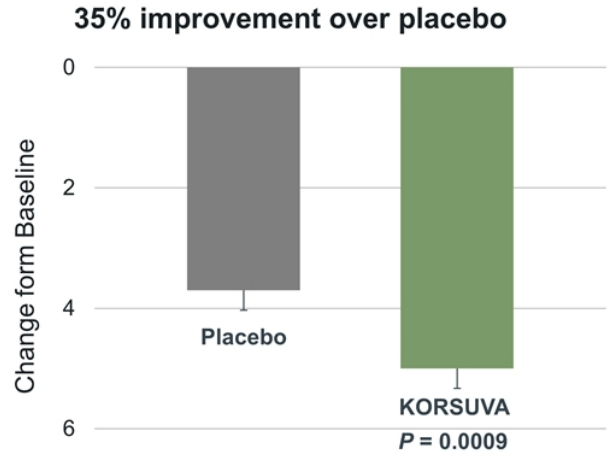
LS Means over time

LS Means from MMRM with terms for treatment group, week, week by treatment interaction, baseline score and strata
Missing data imputed using multiple imputation (MI) under missing at random (MAR) assumption

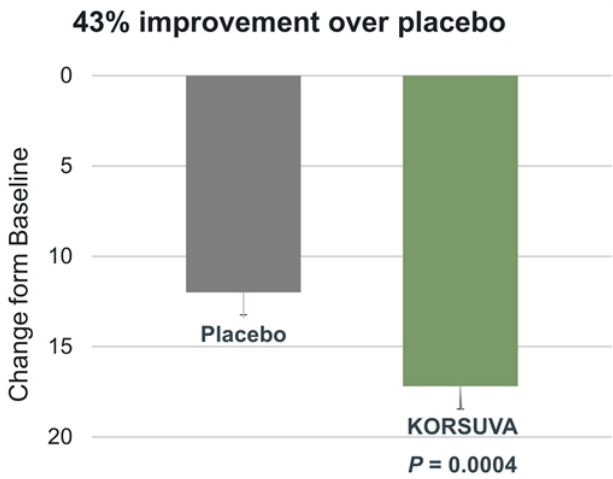
Secondary Endpoints: 5D-Itch and Skindex-10 at Week 12

Demonstrated significant improvements in itch-related QoL measures

5-D



Skindex-10



LS Mean, standard error & P-value based on ANCOVA with terms for treatment group, baseline score, and strata
Missing values imputed using multiple imputation (MI) under MAR assumption

KALM-1 Phase 3 Pivotal Results Summary

Study met primary and all secondary endpoints

Endpoints at Week 12 KORSUVA 0.5 mcg/kg vs placebo	*P* Value
Primary ○ Proportion subjects with ≥3 point improvement in weekly mean of daily WI-NRS	0.000019
Secondary 1) Proportion subjects ≥4 point improvement in weekly mean of daily WI-NRS	0.000032
2) Change from baseline in 5-D Itch score	0.0009
3) Change from baseline in total Skindex-10 score	0.0004

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KALM-1 Summary of Safety

Treatment-emergent Adverse Events	Placebo N = 188 n (%)	KORSUVA N = 189 n (%)
Subjects with at least one treatment-emergent adverse event	117 (62)	130 (69)
Subjects with at least one serious treatment-emergent adverse event	41 (22)	49 (26)
Deaths	2 (1)	2 (1)
Non-fatal SAEs	39 (21)	47 (25)
Treatment-emergent adverse events resulting in discontinuation	9 (4.8)	14 (7.4)

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KALM-1 Most Commonly Reported TEAEs

Treatment-emergent Adverse Events at ≥5% frequency	Placebo N = 188 n (%)	KORSUVA N = 189 n (%)
Diarrhea	7 (3.7)	18 (9.5)
Dizziness	2 (1.1)	13 (6.9)
Vomiting	6 (3.2)	10 (5.3)
Nasopharyngitis	10 (5.3)	6 (3.2)

Conclusions

- KALM-1 Phase 3 pivotal study KALM-1 with KORSUVA™ Injection met primary and all secondary endpoints, demonstrating statistically robust improvements in itch intensity and itch-related quality of life measures
- KORSUVA™ Injection was generally well tolerated with a safety profile consistent with prior studies in this patient population
- Second pivotal Phase 3 study (KALM-2) continues to enroll with top line data expected in 2H 2019 based on current enrolment expectations