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 21, 2020**

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 April 21, 2020, Cara Therapeutics, Inc. (the "Company") issued a press release announcing top-line data from its KALM-2 pivotal Phase 3 trial of KORSUVA™ (CR845/difelikefalin) Injection in hemodialysis patients with moderate-to-severe chronic kidney disease-associated pruritus ("CKD-aP"). The Company will hold a conference call to discuss the results at 8:30 a.m. ET on April 21, 2020. 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 April 21, 2020, the Company issued a press release announcing top-line data from its KALM-2 pivotal Phase 3 trial of KORSUVA Injection in hemodialysis patients with moderate-to-severe CKD-aP.

KALM-2 is a Phase 3, global, multicenter, randomized, double-blind, placebo-controlled, 12-week trial (with a 52-week open label extension phase) designed to evaluate the safety and efficacy of 0.5 mcg/kg KORSUVA Injection in 473 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 itching intensity numeric rating scale, or WI-NRS, score at week 12. Secondary endpoints include assessment of the proportion of patients achieving four-point or greater improvement from baseline in weekly mean of the daily 24-hour WI-NRS score at week 12, as well as itch-related quality of life changes measured using the validated self-assessment Skindex-10 and 5-D itch scales.

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 WI-NRS score at week 12 was 54% vs. 42% for patients on placebo (p=0.02).

Key Secondary Endpoint: 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 41% vs. 28% for patients on placebo (p=0.01).

Itch-Related Quality of Life Measures. Patients on KORSUVA Injection experienced a 12% and 29% numerical improvement in the average total Skindex-10 and total 5-D Itch scores, respectively, which did not meet statistical significance.

Safety and Tolerability: KORSUVA was generally well-tolerated with a safety profile consistent with that seen in KALM-1 and in the KORSUVA clinical program in patients with CKD-aP. 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 $\geq$5% of patients were diarrhea (8.1% KORSUVA vs. 5.5% placebo), fall (6.8% KORSUVA vs. 5.1% placebo), vomiting (6.4% KORSUVA vs. 5.9% placebo), nausea (6.4% KORSUVA vs. 4.2% placebo) and dizziness (5.5% KORSUVA vs. 5.1 % placebo).

The Company remains on track to submit its New Drug Application to the U.S. Food and Drug Administration for KORSUVA Injection in the second half of 2020, and anticipates submitting for marketing approval to the European Medicines Agency shortly thereafter.

Forward-looking Statements

Statements contained in this Current Report on Form 8-K 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 planned timing of future regulatory submissions. 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 the Company's filings with the Securities and Exchange Commission, including the "Risk Factors" section of the Company's Annual Report on Form 10-K for the year ended December 31, 2019 and its other documents subsequently filed with or furnished to the Securities and Exchange Commission. All forward-looking statements contained herein speak only as of the date on which they were made. Except to the extent required by law, the Company undertakes no obligation to update such statements to reflect events that occur or circumstances that exist after the date on which they were made.

Item 9.01 Financial Statements and Exhibits.

(d) Exhibits

Exhibit No.	
99.1	Press release dated April 21, 2020.
99.2	Presentation dated April 21, 2020.

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/ Derek Chalmers, Ph.D., D.Sc.
Derek Chalmers, Ph.D., D.Sc.
President and Chief Executive Officer

Date: April 21, 2020

Exhibit 99.1

Cara Therapeutics and Vifor Fresenius Medical Care Renal Pharma Announce Positive Results From Global KALM-2 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=0.02) -***

- ***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=0.01) -***

- ***KORSUVA Injection NDA and MAA submission expected in the second half of 2020 -***

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

STAMFORD, Conn. and St. Gallen, CH, April 21, 2020 – Cara Therapeutics, Inc. (Nasdaq:CARA) and Vifor Fresenius Medical Care Renal Pharma (VFMCRP), today announced positive topline data from Cara's KALM-2 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 very pleased with the positive topline data from our global, pivotal Phase 3 trial of KORSUVA Injection, which reinforce the robust results we reported from our U.S. KALM-1 Phase 3 trial last year," said Derek Chalmers, Ph.D., D.Sc., President and Chief Executive Officer of Cara Therapeutics. "With these data in hand, we remain on track to submit our New Drug Application (NDA) for KORSUVA Injection in the second half of this year to the U.S. Food and Drug Administration (FDA) and, working with our partner Vifor Fresenius Medical Care Renal Pharma, plan to submit for Marketing Authorization Approval (MAA) to the European Medicines Agency (EMA) shortly thereafter."

"I continue to be very impressed by the robust efficacy of KORSUVA for the treatment of pruritus in our patients undergoing hemodialysis," said Steven Fishbane, M.D., Chief, Division of Kidney Disease and Hypertension, Northwell Health and Professor of Medicine at Hofstra/Northwell. "Itching is a real issue for our hemodialysis patients and there are no approved treatments in the U.S. or Europe so I am encouraged by the potential of this drug to address a significant unmet need for our patients."

“We are delighted with this outcome and congratulate the Cara team on the positive topline Phase 3 data on KORSUVA Injection in hemodialysis patients with moderate-to-severe pruritus,” said Stefan Schulze, Vifor Pharma President of Executive Committee and Chief Operating Officer. “KORSUVA Injection has the potential to serve as a breakthrough therapeutic for treating this serious itching condition in hemodialysis patients, and is a natural fit to our leading nephrology-focused product portfolio. We are committed to making KORSUVA Injection available as quickly as possible to hemodialysis patients, who urgently need effective therapy.”

CKD-aP is an intractable systemic itch condition that occurs with high frequency and intensity in patients undergoing hemodialysis. Multiple studies estimate that at least 40% of dialysis patients suffer from pruritus. The FDA has granted Breakthrough Therapy designation to KORSUVA Injection for this indication.

KALM-2 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 54% versus 42% for patients on placebo (p= 0.02).

- *Key Secondary Endpoint*: 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 41% versus 28% for patients on placebo (p= 0.01).

- *Itch-Related Quality of Life Measures*: Patients on KORSUVA Injection experienced a 12% and 29% numerical improvement in the average total Skindex-10 and total 5-D Itch scores, respectively, which did not meet statistical significance.

KALM-2 Safety and Tolerability:

KORSUVA Injection was generally well-tolerated with a safety profile consistent with that seen in KALM-1 and the KORSUVA clinical program in patients with CKD-aP. 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 $\geq$5% of patients were diarrhea (8.1% KORSUVA versus 5.5% placebo), falling (6.8% KORSUVA versus 5.1% placebo), vomiting (6.4% KORSUVA versus 5.9% placebo), nausea (6.4% KORSUVA versus 4.2% placebo) and dizziness (5.5% KORSUVA versus 5.1 % placebo).

VFMCRP License Agreement

In May 2018, Cara licensed worldwide rights, except in the U.S., Japan and South Korea, to commercialize KORSUVA Injection for the treatment of CKD-aP in dialysis patients to VFMCRP, a company that specializes in nephrology therapies. Cara retains full development and commercialization rights for KORSUVA Injection for the treatment of CKD-aP in the U.S. except in the dialysis clinics of Fresenius Medical Care North America (FMCNA), where VFMCRP and Cara will promote KORSUVA Injection under a profit-sharing arrangement based on net FMCNA clinic sales recorded by Cara. Cara will solely promote KORSUVA Injection in all non-FMC clinics in the U.S. and retain all profits from those sales.

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 1681438. A live webcast of the call can be accessed under "Events & Presentations" in the News & Investors section of Cara'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-2 Phase 3 Trial Design

KALM-2 is a Phase 3, global, multicenter, randomized, double-blind, placebo-controlled, 12-week trial (with a 52-week open label extension phase) designed to evaluate the safety and efficacy of 0.5 mcg/kg KORSUVA (CR845/difelikefalin) Injection in 473 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 the proportion of patients achieving four-point or greater improvement from baseline in weekly mean of the daily 24-hour WI-NRS score at week 12, as well as itch-related quality of life changes measured using the validated self-assessment 5-D itch and Skindex-10 scales.

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 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% in patients with end-stage renal disease (ESRD), with approximately 25% of patients reporting severe pruritus. The majority of dialysis patients (approximately 60 to 70%) report pruritus, with 30 to 40% reporting moderate or severe pruritus.[1,2] Recent data from the ITCH National Registry Study showed that among those with pruritus, approximately 59% 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. 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 two Phase 3 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 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.

About Vifor Pharma and Vifor Fresenius Medical Care Renal Pharma Ltd (VFMCRP)

Vifor Pharma Group is a global specialty pharmaceuticals company. It aims to become the global leader in iron deficiency, nephrology and cardio-renal therapies. Vifor Pharma Group consists of the following companies: Vifor Pharma; Vifor Fresenius Medical Care Renal Pharma, a joint company with Fresenius Medical Care; Relypsa; and OM Pharma. Vifor Pharma Group is listed on the Swiss Stock Exchange (SIX Swiss Exchange, VIFN, ISIN: CH0364749348).

Vifor Fresenius Medical Care Renal Pharma Ltd., a common company of Vifor Pharma Group and Fresenius Medical Care, develops and commercialises innovative and high quality therapies to improve the life of patients suffering from chronic kidney disease (CKD) worldwide. The company was founded at the end of 2010 and is owned 55% by Vifor Pharma Group and 45% by Fresenius Medical Care.

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 planned timing of future regulatory submissions; the size of the potential markets that are potentially addressable for Cara’s product candidates, including the pruritus market and the potential for KORSUVA Injection to be a therapeutic option for CKD-aP. 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, 2019 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 for Dialysis Patients

KALM-2
Phase 3 Pivotal Topline Results

April 21, 2020

CARA THERAPEUTICS

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 planned regulatory submissions; the size of the potential markets that are potentially addressable for the Company's product candidates, including the pruritus market; the potential commercialization of KORSUVA™ in the licensed territories; and the potential benefits of license agreements entered by the Company.
- 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, 2019, 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.

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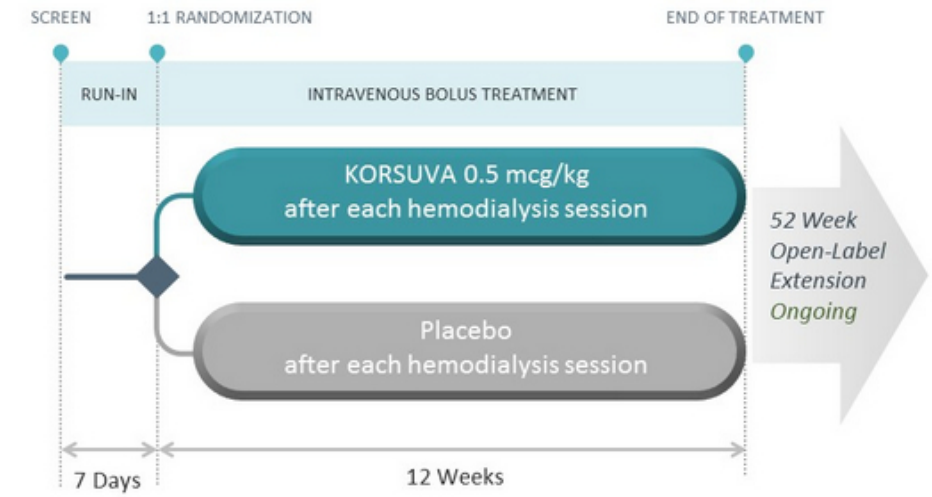
KALM-2: Multicenter Global Pivotal Study Design



Subjects Undergoing Hemodialysis With Moderate-to-Severe Pruritus (WI-NRS ≥ 5)

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 in WI-NRS
- Proportion of subjects achieving ≥3 point or ≥4 point improvement in WI-NRS at Weeks 4 & 8
- Change from baseline in itch-related Quality of Life as measured by Skindex-10 and 5-D Itch questionnaires

Safety assessments

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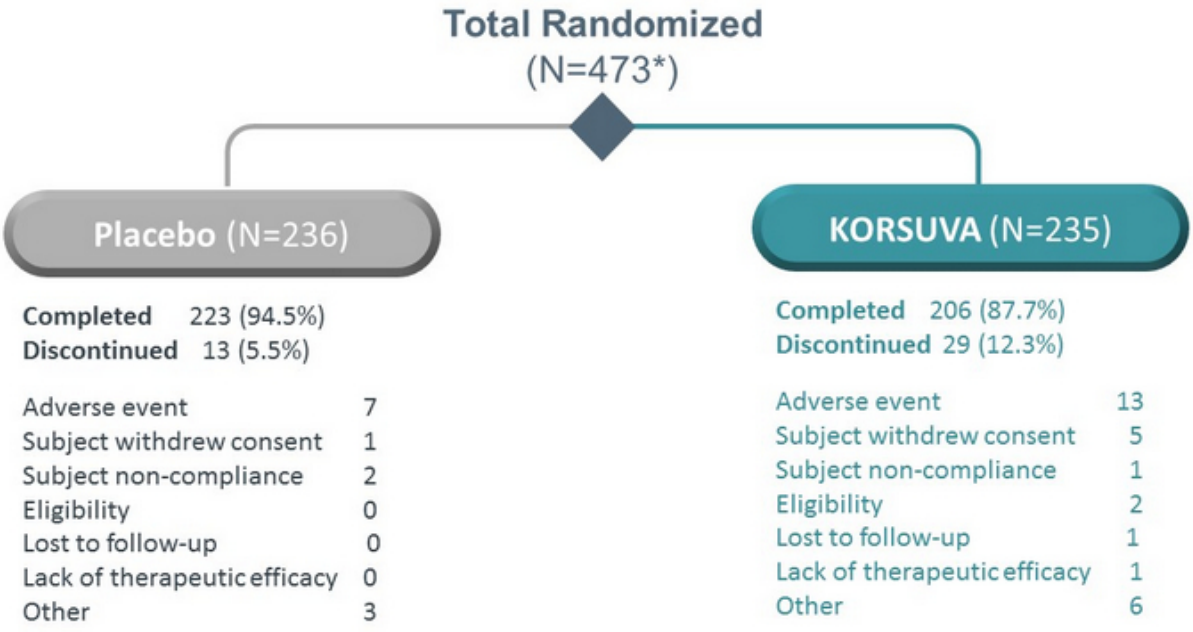
Subject Disposition in Double-blind Treatment Period



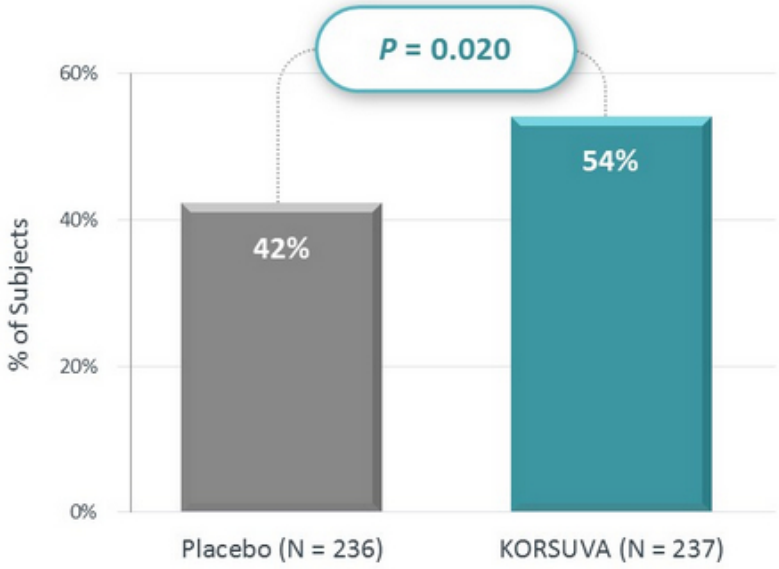
*2 subjects were randomized to KORSUVA but did not receive study drug

Baseline Characteristics

Baseline Characteristics Mean (SD) or %	Placebo N = 236	KORSUVA N = 235
Years Undergoing Hemodialysis	5.1 (4.33)	4.8 (4.59)
Years of Pruritus	3.2 (3.18)	3.2 (4.57)
Use of Anti-Itch Medication	36%	37 %
Worst Itching Intensity NRS	7.1 (1.4)	7.3 (1.4)
5-D Itch Total Score	16.2 (3.3)	16.7 (3.5)
Skindex-10 Total Score	34.2 (14.7)	35.5 (15.0)

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
Skindex-10 scale ranges from 0 to 60

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



- KORSUVA subjects > 1.6 times more likely to experience a clinically meaningful reduction in itch (≥3 point improvement)
- Significant improvement started at Week 2 (P = 0.003)

Estimated percentage & P-value based on a logistic regression model with terms for treatment group, baseline WI-NRS score, region and strata
Missing data imputed using multiple imputation (MI) under missing at random (MAR) assumption
Odd Ratio: 1.61

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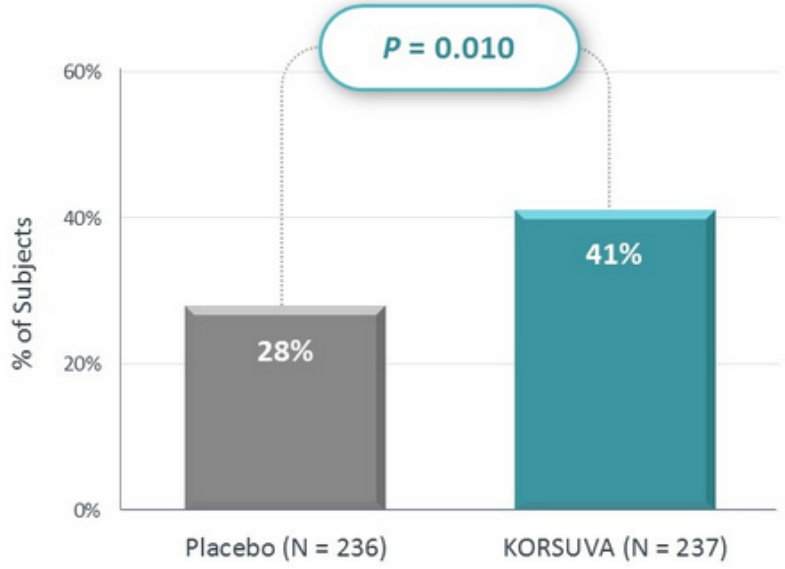
Key Secondary Endpoint: ≥4 point improvement WI-NRS (Week 12)



- KORSUVA subjects > 1.8 times more likely to experience ≥4 point improvement
- Significant improvement started at Week 3 (P = 0.018)

Estimated percentage & P-value based on a logistic regression model with terms for treatment group, baseline WI-NRS score, region and strata
Missing data imputed using multiple imputation (MI) under missing at random (MAR) assumption
Odd Ratio: 1.77

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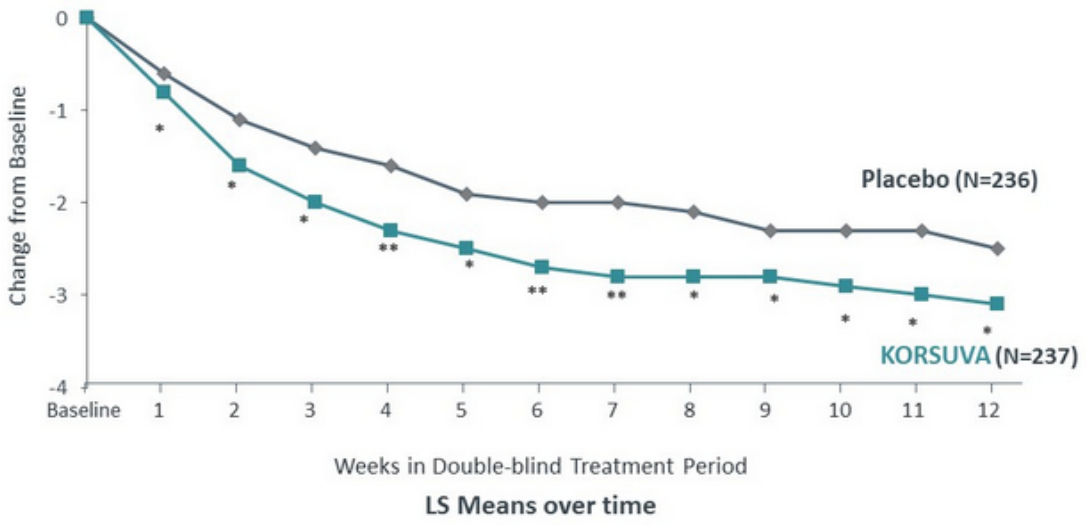
Change from Baseline in WI-NRS Over Time

Significant differences observed in WI-NRS starting at Week 1 and sustained through treatment period



* $P<0.05$, ** $P<0.001$

LS Means from MMRM with terms for treatment group, week, week by treatment interaction, baseline score, region and strata

Missing data imputed using multiple imputation (MI) under missing at random (MAR) assumption

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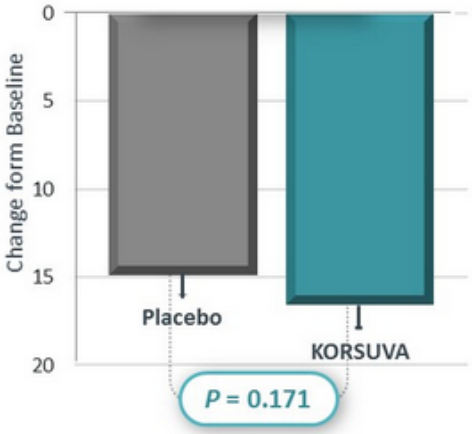
Other Secondary Endpoints:
Skindex-10 and 5-D Itch Total Score at Week 12

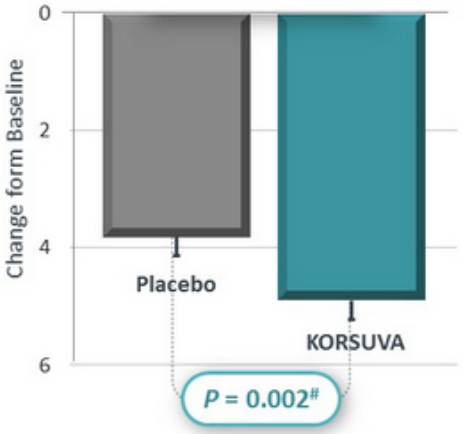
Skindex-10

12% improvement over placebo



5-D

29% improvement over placebo



Itch severity related domains in both scales were significant (P = 0.003 to 0.047) and consistent with WI-NRS improvement

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

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Summary of Adverse Events

Treatment-emergent Adverse Events (TEAE)	Placebo N = 236 n (%)	KORSUVA N = 235 n (%)
Subjects with at least one TEAE	145 (61)	160 (68)
Subjects with at least one serious TEAE	51 (22)	58 (25)
Number of deaths	2 (1)	2 (1)

Safety analyses performed in the safety population, defined as all randomized patients who received ≥1 dose of study drug based on actual treatment received.

Most Commonly Reported TEAEs

Treatment-emergent Adverse Events at ≥5% frequency	Placebo N = 236 n (%)	KORSUVA N = 235 n (%)
Diarrhea	13 (5.5)	19 (8.1)
Fall	12 (5.1)	16 (6.8)
Dizziness	12 (5.1)	13 (5.5)
Vomiting	14 (5.9)	15 (6.4)
Nausea	10 (4.2)	15 (6.4)

Safety analyses performed in the safety population, defined as all randomized patients who received ≥1 dose of study drug based on actual treatment received.

Executive Summary & Next Steps

- KALM-2 Phase 3 trial of KORSUVA™ injection met primary & key secondary endpoints:
  - Both 3-point and 4-point improvement in WI-NRS endpoints achieved
  - KORSUVA™ Injection provided a rapid and sustained reduction of pruritus
- Numerical improvement in itch-related quality of life measures
- Safety profile consistent with KALM-1 and CKD-aP clinical program
- Key efficacy results replicated KALM-1 US Phase 3 pivotal trial (Fishbane et al., N Engl J Med 2020; 382:222-232)

➢ **Successful outcome of KALM-2 trial supports NDA submission of KORSUVA™ injection for the treatment of moderate-to-severe CKD-aP in hemodialysis patients planned for 2H, 2020**

CARA

Acknowledgement

We thank all the investigators and patients who participated in this study and provided support for this program.