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): **December 3, 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 December 3, 2019, Cara Therapeutics, Inc. (the "Company") issued a press release and held a conference call announcing top-line data from its Phase 2 clinical trial of Oral KORSUVA for chronic kidney disease-associated pruritus ("CKD-aP"). A copy of the press release and the presentation 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 December 3, 2019, the Company issued a press release announcing top-line data from its Phase 2 clinical trial of Oral KORSUVA for CKD-aP.

The Phase 2, multicenter, randomized, double-blind, placebo-controlled 12-week trial was designed to evaluate the safety and efficacy of three tablet strengths (0.25 mg, 0.5 mg and 1 mg, once daily administration) of Oral KORSUVA versus placebo in approximately 240 stage III-V (moderate to severe) CKD patients with moderate-to-severe pruritus. The primary efficacy endpoint was the change from baseline in the weekly mean of the daily 24-hour worst itch Numeric Rating Scale ("WI-NRS") score at Week 12 of the treatment period. Secondary endpoints included change from baseline in itch-related quality of life scores at the end of Week 12, as assessed by the total Skindex-10 and 5-D itch scores, as well as the proportion of patients achieving an improvement from baseline ≥3 points with respect to the weekly mean of the daily 24-hour WI-NRS score at Week 12.

Primary Endpoint: Patients treated with the 1 mg once daily tablet strength of Oral KORSUVA achieved the primary endpoint of statistically significant reduction in weekly mean of the daily WI-NRS scores versus placebo after the 12-week treatment period (-4.4 KORSUVA vs. -3.3 placebo, p=0.018). The treatment effect was statistically significant after 2 weeks of treatment and sustained through the 12-week treatment period.

Secondary Endpoints:

Proportion of Responders. The proportion of patients on 1 mg tablet strength achieving a 3 point or greater improvement from baseline in the weekly mean of the daily WI-NRS score at Week 12 was 72% versus 58% for patients on placebo but did not achieve statistical significance.

Itch-Related Quality of Life Measures. Patients on Oral KORSUVA showed dose-related improvements vs. placebo in itch-related quality of life endpoints as measured using self-assessment Skindex-10 and 5-D Itch scales but did not achieve statistical significance.

Safety and Tolerability: Oral KORSUVA was generally well tolerated with a safety profile consistent with that seen in earlier KORSUVA clinical trials. Overall, the incidence of treatment-emergent adverse events ("AEs") were similar across KORSUVA and placebo groups. The most common treatment-emergent AEs reported in >5% of patients in the 1 mg KORSUVA group versus placebo were dizziness (7.5% KORSUVA vs. 0% placebo), fall (6% KORSUVA vs. 0% placebo), diarrhea (6% KORSUVA vs. 1.5% placebo) and constipation (KORSUVA 6% vs. 3% placebo).

Item 9.01 Financial Statements and Exhibits.

(d) Exhibits

Exhibit No.	
99.1	Press release dated December 3, 2019.
99.2	Presentation dated December 3, 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: December 3, 2019

Exhibit 99.1

Cara Therapeutics Announces Positive Topline Data From Phase 2 Trial of Oral KORSUVA™ in Chronic Kidney Disease Patients with Moderate-to-Severe Pruritus

- *Met primary endpoint with statistically significant reduction in mean worst itching intensity NRS scores with 1 mg tablet strength vs placebo after 12-week treatment period (p=0.018) –*

- *Oral KORSUVA™ well-tolerated after 12 weeks of treatment –*

- *Conference call today at 8:30 a.m. ET -*

STAMFORD, Conn., December 3, 2019 – Cara Therapeutics, Inc. (Nasdaq: CARA), a biopharmaceutical company focused on developing and commercializing new chemical entities designed to alleviate pruritus by selectively targeting peripheral kappa opioid receptors, today announced positive topline results from its Phase 2 dose-ranging trial of Oral KORSUVA™ (CR845/difelikefalin) for the treatment of pruritus in patients with stage III-V (moderate-to-severe) chronic kidney disease (CKD).

“CKD-associated pruritus remains a significant unmet need for approximately one-third of diagnosed CKD patients in the U.S.,” said Derek Chalmers, Ph.D., D.Sc., President and Chief Executive Officer of Cara Therapeutics. “We are pleased that this Phase 2 study has successfully identified an appropriate tablet strength of Oral KORSUVA to carry forward into a pivotal Phase 3 registration program which we expect to initiate next year.”

“These exciting results underscore Oral KORSUVA’s potential to be the first approved therapy in the U.S. for CKD patients suffering from moderate-to-severe pruritus,” said Gil Yosipovitch, M.D., Professor, Dr. Phillip Frost Department of Dermatology and Cutaneous Surgery and Director of the Miami Itch Center. “There is an unmet medical need for an effective long-term therapy for treating intractable pruritus and the results from this trial suggest Oral KORSUVA holds great promise for CKD patients.”

Phase 2 Trial

The Phase 2, multicenter, randomized, double-blind, placebo-controlled 12-week trial was designed to evaluate the safety and efficacy of three dose levels (0.25 mg, 0.5 mg and 1 mg, once daily) of Oral KORSUVA vs. placebo (randomized 1:1:1:1) in approximately 240 stage III-V CKD patients with moderate-to-severe pruritus.

The primary efficacy endpoint was the change from baseline in the weekly mean of the daily 24-hour Worst Itching Intensity Numeric Rating Scale (WI-NRS) score at Week 12 of the treatment period for any of the three tablet strengths vs. placebo. Secondary endpoints included change from baseline in itch-related quality of life scores at the end of Week 12, as assessed by the total Skindex-10 and 5-D itch scales, as well as the proportion of patients achieving an improvement from baseline of ≥3 points with respect to the weekly mean of the daily 24-hour Worst Itch NRS score at Week 12.

Primary Endpoint: Patients treated with the 1 mg tablet strength of Oral KORSUVA™ achieved the primary endpoint of statistically significant reduction in weekly mean of the daily WI-NRS scores vs. placebo after the 12-week treatment period (-4.4 KORSUVA vs. -3.3 placebo, p=0.018). The treatment effect was statistically significant after two weeks of treatment and sustained through the 12-week treatment period.

Secondary Endpoints: The proportion of patients on 1 mg tablet strength achieving a 3 point or greater improvement from baseline in the weekly mean of the daily WI-NRS score at week 12 was 72% vs. 58% for placebo but did not achieve statistical significance.

Patients on 1 mg tablet strength showed positive improvements vs. placebo in itch related quality of life endpoints as measured using self-assessment Skindex-10 and 5-D Itch scales but did not achieve statistical significance.

Safety and Tolerability:

Oral KORSUVA was generally well-tolerated with a safety profile consistent with that seen in earlier KORSUVA clinical trials. Overall, the incidence of treatment emergent adverse events (AEs) were similar across KORSUVA and placebo groups. The most common treatment emergent AEs reported in >5% of patients in the 1 mg KORSUVA group vs. placebo were dizziness (7.5% KORSUVA vs. 0% placebo), fall (6% KORSUVA vs. 0% placebo), diarrhea (6% KORSUVA vs. 1.5% placebo) and constipation (KORSUVA 6% vs. 3% placebo).

Conference Call

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

To participate in the conference call, please dial (855) 445-2816 (domestic) or (484) 756-4300 (international) and refer to conference ID 8695654. 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.

About CKD-Associated Pruritus (CKD-aP)

CKD-aP is an intractable systemic itch condition that occurs with high frequency and intensity in patients with CKD undergoing hemodialysis and peritoneal dialysis. Pruritus has also been reported in patients with stage III-V CKD who are not on dialysis. According to estimates from the Centers for Disease Control and Prevention, approximately 15% of the adult population in the United States, or 30 million people, suffer from CKD, with an estimated 50% in stages III-V. Of the patients diagnosed with stage III-V CKD, approximately 25% suffer from moderate-to-severe pruritus.[1] 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/end-stage renal disease, most afflicted patients will continue to have symptoms for months or years with currently employed antipruritic treatments, such as antihistamines and corticosteroids, which are 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.[4]

References:

1. Centers for Disease Control and Prevention: Chronic Kidney Disease (CKD) Surveillance Project. National Health and Nutrition Examination Survey. 2014.
2. Sukul N, et al. Pruritus in Chronic Kidney Disease Patients: Early Results from CKDopps. ERA-EDTA Abstract. December 2016.
3. IMS Pruritus Market Landscape Analysis. September 2014.
4. 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 both Phase 3 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). KORSUVA Injection is currently being investigated in pivotal Phase 3 trials in hemodialysis patients with CKD-aP. Oral KORSUVA is in Phase 2 trials for the treatment of pruritus in patients with CKD, atopic dermatitis and primary biliary cholangitis (PBC).

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 the ongoing trials and future development of the Company's product candidates, including the planned Phase 3 registration trials of Oral KORSUVA, as well as the potential for Oral KORSUVA to be approved for treatment of CKD-associated pruritus. 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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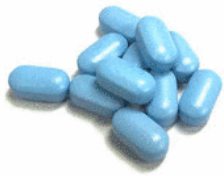
Oral KORSUVA™ for CKD-associated Pruritus: Phase 2 Topline Results

A Multicenter, Double-Blind, Randomized, Placebo-Controlled Study to Evaluate the Safety and Efficacy of Oral KORSUVA™ (CR845, Difelikefalin) in Chronic Kidney Disease Patients 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; the potential results of ongoing and planned clinical trials; future regulatory and development milestones for the Company's product candidates; and the size of the potential markets that are potentially addressable for the Company's product candidates, including the pruritus market

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.

CARA THERAPEUTICS

US Market Opportunity in CKD-aP: Non-Dialysis

~7.3 million
diagnosed with CKD (IQVIA est)

33%
receive pruritus tx

Per NKF, CKD is a big under-recognized US public health issue

- ~30 million people affected (causes more deaths than breast/ prostate cancer)

No FDA approved therapies – large unmet medical need

- Commonly used medications: anti-histamines, corticosteroids, gabapentin, anti-depressants etc.

Oral KORSUVA™, if approved for pre-dialysis patients, would not fall under ESRD bundle payment system

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Executive Summary

- CR845-210301 Phase 2 study of Oral KORSUVA™ met the primary endpoint*
- A positive dose-related trend was observed for all secondary endpoints.
- Oral KORSUVA was generally well tolerated with the safety profile consistent with prior studies.
- Oral KORSUVA 1mg was identified as the appropriate dose to be studied in Phase 3.

** The primary endpoint was defined as the Change from baseline in weekly mean of daily Worst Itching Intensity NRS (WI-NRS) score and the study would be considered positive if at least one dose achieved statistical significance versus placebo in the primary endpoint and exhibited a favorable safety profile*

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Oral KORSUVA™ for CKD-aP

- Phase 2 dose ranging study to assess safety and efficacy of 3 dose levels of oral KORSUVA on itch severity and itch-related QoL compared to placebo across diverse CKD population
- Enrolled Stage 3 to 5 CKD patients (non-dialysis and dialysis) with chronic moderate to severe pruritus
- Stratified to treatment based on renal disease status:
  - Stage 3 CKD non-dialysis
  - Stage 4 or 5 CKD non-dialysis
  - Stage 4 or 5 CKD on hemodialysis (20% enrollment cap)
- The study to be considered positive if at least one dose is identified that achieves statistical significance versus placebo in the primary endpoint and exhibits a favorable safety profile.

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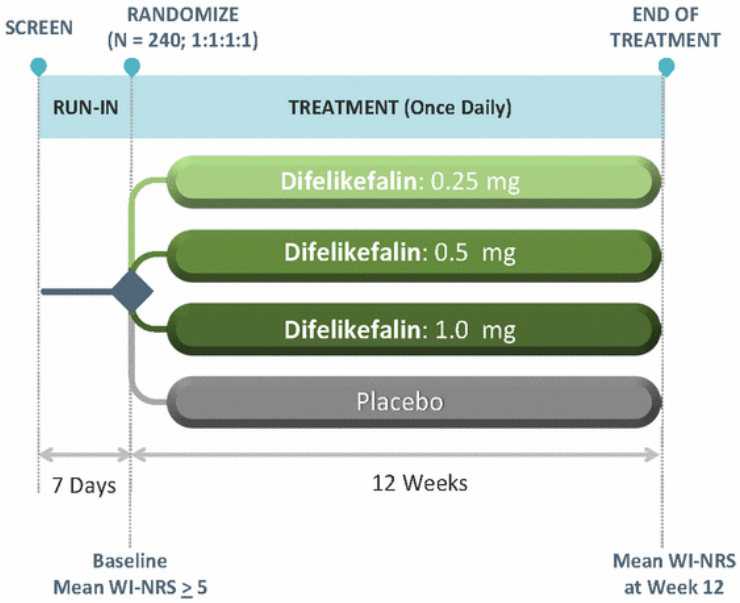
Oral KORSUVA™ for CKD-aP: Ph 2 Trial Design



Endpoints: Week 12

Primary

- Change from baseline in weekly mean of daily Worst Itching Intensity NRS (WI-NRS) score

Secondary

- Change from baseline in itch-related QoL
  - ✓ Skindex-10
  - ✓ 5-D Itch
- Proportion of subjects achieving >3 points improvement from baseline in weekly mean of daily WI-NRS score

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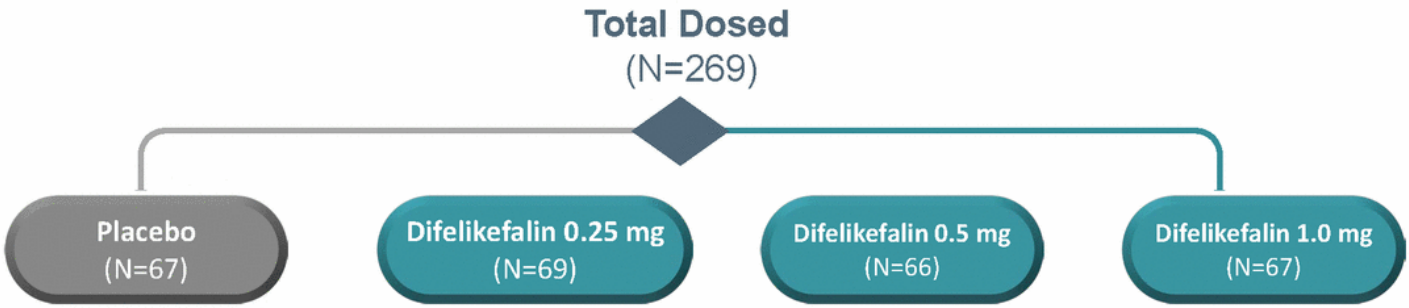
Oral KORSUVA™ for CKD-aP: Patient Disposition



	Placebo (N=67)	Difelikefalin 0.25 mg (N=69)	Difelikefalin 0.5 mg (N=66)	Difelikefalin 1.0 mg (N=67)
Completed	**57** (85%)	**60** (87%)	**57** (86%)	**54** (81%)
Discontinued	**10** (15%)	**9** (13%)	**9** (14%)	**13** (19%)
Adverse event	4	3	6	8
Subject withdrew consent	3	2	2	3
Subject non-compliance	0	2	0	0
Eligibility	0	0	0	0
Lost to follow-up	0	2	0	0
Other	3	0	1	2

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Oral KORSUVA™ for CKD-aP: Demographics

Demographic Characteristic	Placebo	Difelikefalin		
N (%)	N = 67	0.25 mg N = 69	0.5 mg N = 66	1.0 mg N = 67
Males	37 (55)	34 (49)	33 (50)	35 (52)
Age - Mean (SD)	66 (12)	66 (11)	69 (12)	68 (11)
Hispanic or Latino	34 (51)	30 (44)	31 (47)	33 (49)
White	47 (70)	49 (71)	49 (74)	48 (72)
Black	17 (25)	17 (25)	12 (18)	15 (22)
Asian	2 (3)	1 (1)	5 (8)	4 (6)

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Oral KORSUVA™ for CKD-aP: Baseline Disease Characteristics

Baseline Characteristics	Placebo	Difelikefalin		
N (%)	N = 67	0.25 mg N = 69	0.5 mg N = 66	1.0 mg N = 67
Stage 3 CKD Non-Dialysis (30 ≤ eGFR <60mL/min/1.73m²)	40 (60)	41 (59)	38 (58)	40 (60)
Stage 4 or 5 CKD Non-Dialysis (eGFR <30 mL/min/1.73m²)	15 (22)	16 (23)	16 (24)	15 (22)
Stage 4 or 5 CKD on Hemodialysis (eGFR <30 mL/min/1.73m²)	12 (18)	12 (17)	12 (18)	12 (18)
History of Diabetes	51 (76)	46 (67)	45 (68)	48 (72)
History of Hypertension	66 (99)	63 (91)	61 (92)	61 (91)

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Oral KORSUVA™ for CKD-aP: Baseline Itch Characteristics

Baseline Itch Characteristics	Placebo	Difelikefalin		
Mean (SD)	N = 67	0.25 mg N = 69	0.5 mg N = 66	1.0 mg N = 67
Baseline Worst Itching Intensity NRS	6.98 (1.10)	7.24 (1.17)	7.04 (1.20)	7.04 (1.27)
Baseline Skindex-10 Total Score	34.9 (14.3)	36.5 (13.3)	33.1(14.3)	35.7(13.9)
Baseline 5-D Itch Total Score	16.8 (3.1)	16.2 (3.6)	16.2 (3.1)	16.4 (2.7)

NRS: Numeric Rating Scale (0 to 10) where 0 = no itch and 10 = worst itching imaginable
5-D Itch score ranges from 5 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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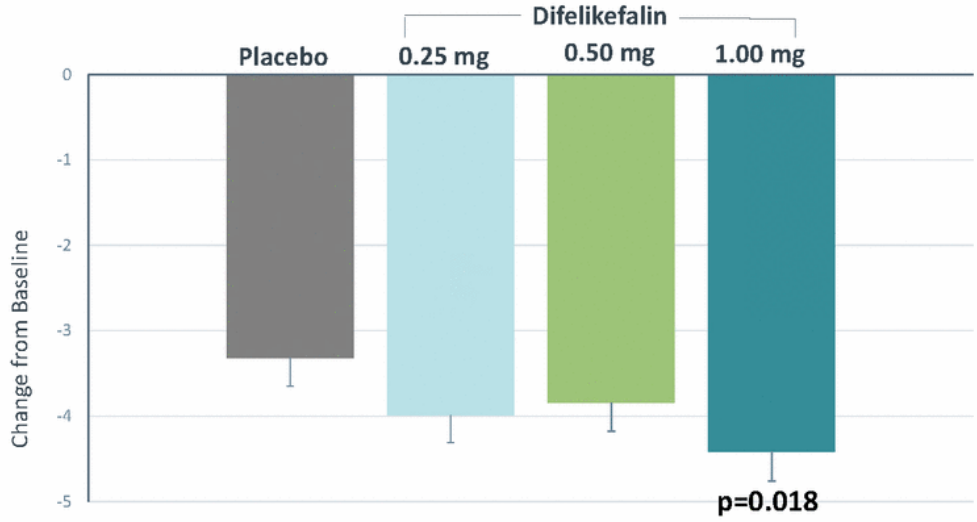
Primary Endpoint: Change from Baseline to Week 12 for WI-NRS

Significant difference in WI-NRS in patients treated with 1 mg oral KORSUVA™ compared to placebo



LS Mean from MMRM with terms for treatment group, week, week by treatment interaction as fixed effects; baseline score and strata as covariates; patient as a repeated measures
Missing data imputed using multiple imputation (MI) under missing at random (MAR) assumption

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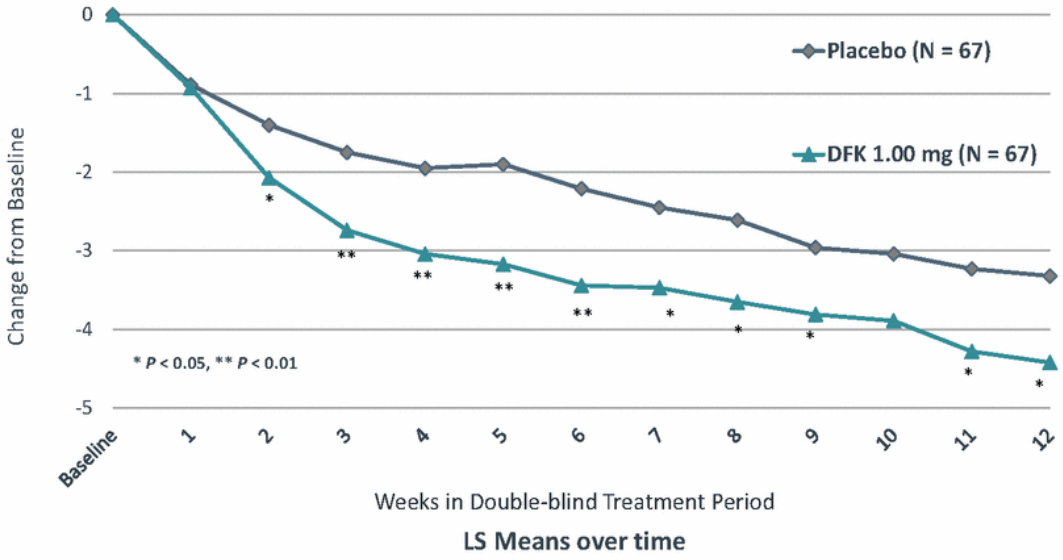
Change in Worst Itching Intensity NRS Over Time

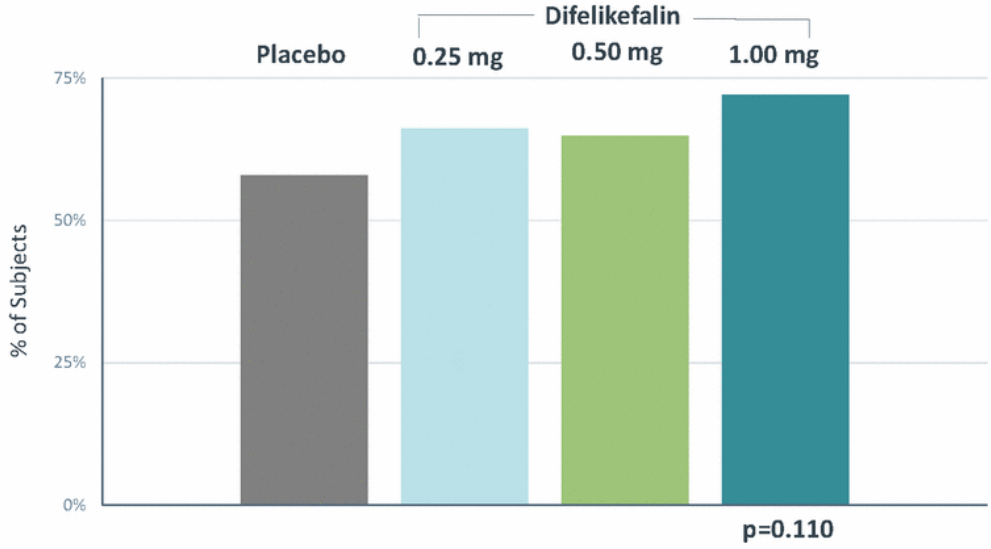
Significant differences between 1mg oral KORSUVA and placebo observed in WI-NRS starting at week 2



LS Mean from MMRM with terms for treatment group, week, week by treatment interaction as fixed effects; baseline score and strata as covariates; patient as a repeated measures
Missing data imputed using multiple imputation (MI) under missing at random (MAR) assumption

Secondary Endpoint: ≥ 3 point improvement in WI-NRS at week 12

72% of Oral KORSUVA 1.0 mg subjects experienced ≥ 3 point improvement from baseline



Estimated percentage; P-values; and Odds ratios are based on a logistic regression model with terms for treatment group, baseline WI-NRS score, and renal disease status
Missing data imputed using multiple imputation (MI) under missing at random (MAR) assumption

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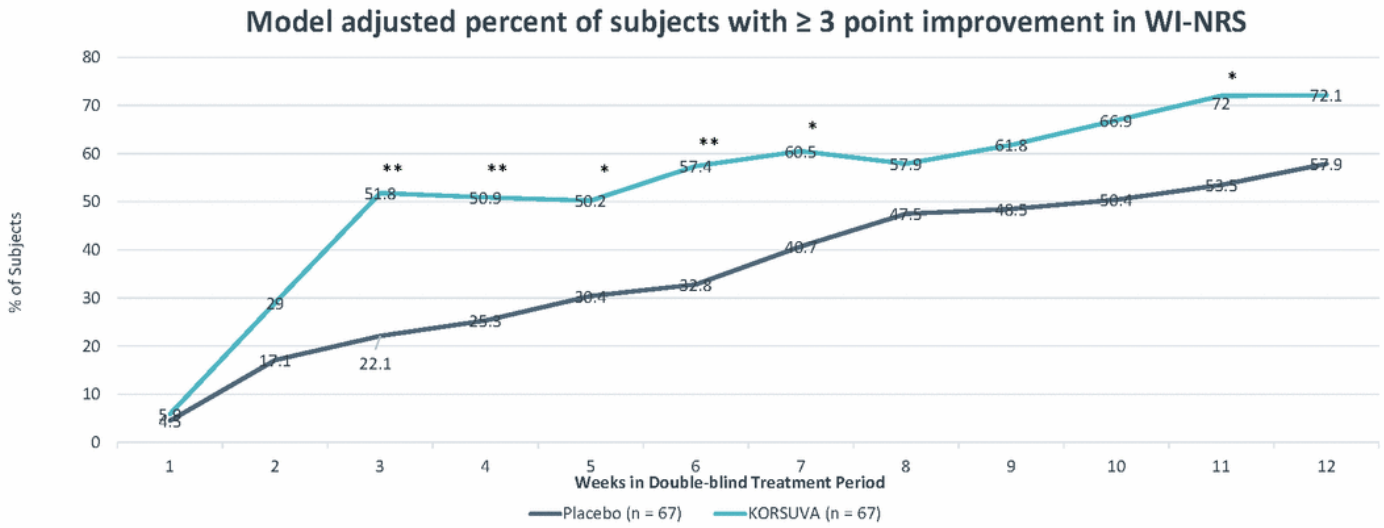
Proportion of subjects with ≥ 3 point improvement in WI-NRS over time



* $P < .05$, ** $P < .01$

Estimated percentage & P-value based on a logistic regression model with terms for treatment group, baseline WI-NRS score, and renal disease status

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

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Secondary Endpoints - Change from Baseline to Week 12 for QoL (Skindex-10 and 5-D Itch Scales)

- Subjects on Oral KORSUVA showed dose-related improvements vs. placebo in both Skindex-10 and 5D- Itch.
- An approximate 20% improvement over placebo was observed in both Skindex-10 and 5D-Itch in the 1mg group but did not achieve statistical significance.

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Oral KORSUVA™ for CKD-aP: Summary of Adverse Events

N (%)	Placebo N = 67	Difelikefalin 0.25 mg N = 69	Difelikefalin 0.5 mg N = 66	Difelikefalin 1.0 mg N = 67
Subjects with at least one TEAE	34 (51)	35 (51)	34 (52)	39 (58)
Subjects with at least one serious TEAE	5 (7.5)	9 (13.0)	9 (13.6)	9 (13.4)
Deaths	3	0	0	1
Non-fatal SAEs	2	9	9	8
Subjects with TEAE resulting in treatment discontinuation	5 (7.5)	2 (2.9)	5 (7.6)	9 (13.4)

Reasons for death include acute respiratory failure (Placebo = 2), coronary arterial disease (DFK 1mg = 1) and cardiac arrest (Placebo = 1).

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Oral KORSUVA™ for CKD-aP: Most Commonly Reported TEAEs

N (%)	Placebo N = 67	Difelikefalin 0.25 mg N = 69	Difelikefalin 0.5 mg N = 66	Difelikefalin 1.0 mg N = 67
Dizziness	0	0	2 (3.0)	5 (7.5)
Fall	0	0	3 (4.5)	4 (6.0)
Constipation	2 (3.0)	2 (2.9)	2 (3.0)	4 (6.0)
Diarrhea	1 (1.5)	2 (2.9)	3 (4.5)	4 (6.0)
Fatigue	1 (1.5)	4 (5.8)	1 (1.5)	3 (4.5)
Urinary tract infection	0	4 (5.8)	2 (3.0)	3 (4.5)
Hypertension	1 (1.5)	4 (5.8)	0	1 (1.5)
Gastro-esophageal reflux disease	0	0	4 (6.1)	0

Most common TEAE = incidence ≥ 5% in at least one treatment group and strictly greater than placebo

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Conclusions

- CR845 210301 Phase 2 study of Oral KORSUVA™ met the primary endpoint
- Oral KORSUVA™ was generally well tolerated with a safety profile consistent with prior studies
- Oral KORSUVA™ 1mg was identified as the appropriate dose to be advanced into Phase 3
- Aim to initiate Phase 3 development program in 2020

Acknowledgement

We thank all the investigators and patients who participated in this study.