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): **January 14, 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.

Cara Therapeutics, Inc. (the "Company") updated its corporate presentation, which has been posted on its website and will be used for presentations. A copy of this presentation is furnished as Exhibit 99.1 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, 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 9.01 Financial Statements and Exhibits.

(d) Exhibits

Exhibit No.	
99.1	Presentation dated January 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
Derek Chalmers
Chief Executive Officer
(Principal Executive Officer)

Date: January 14, 2020

Exhibit 99.1

Targeting Pruritus with Novel Peripherally-Restricted Kappa Agonist Therapeutics

JP Morgan Healthcare Conference

January 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 our planned clinical trials and regulatory submissions; the potential results of ongoing and planned clinical trials; future regulatory and development milestones for the Company's product candidates; the size of the potential markets that are potentially addressable for the Company's product candidates, including the pruritus market and the potential commercialization of Korsuva™.

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

Pruritus: Large Opportunity Across Different Disease Areas

Chronic Kidney Disease (CKD) ~40 to 50%

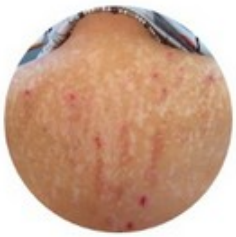
Pruritus occurs in both patients on hemodialysis and those with CKD not yet on dialysis.

Chronic Liver Disease (CLD) ~20% to 30%

Patients with CLD, especially cholestatic liver disease experience significant pruritus .

Atopic Dermatitis (AD) ~100%

Pruritus is a defining symptom of AD



U.S. Patients Treated for Pruritus:

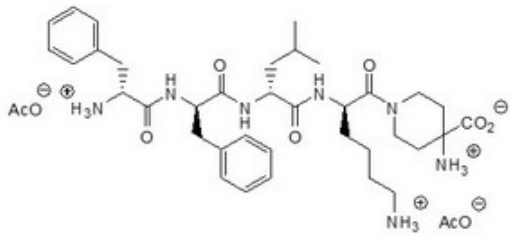
20 Million

SCRIPTS ANNUALLY#

IQVIA Analysis, 2013

CARA THERAPEUTICS

CR845 (KORSUVA™/Difelikefalin):
An Anti-Pruritic Kappa Receptor Agonist



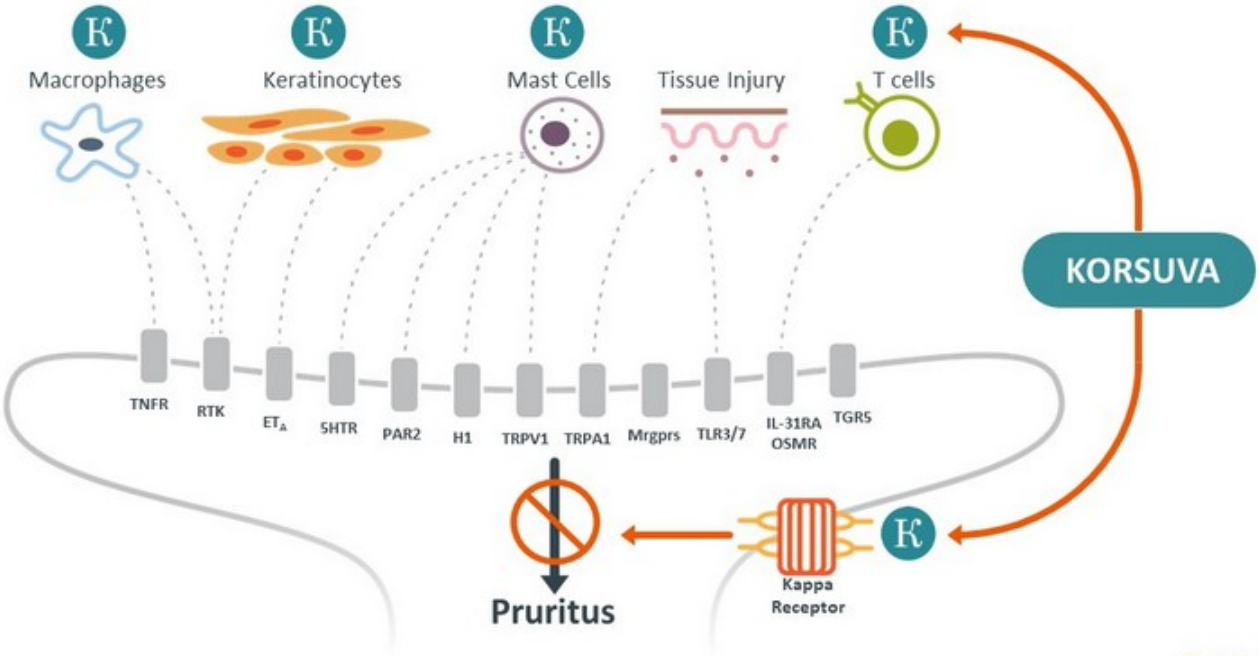
	Human Receptor Binding (nM)		
Drug	Kappa	Mu	Delta
CR845	0.16	>10,000	>10,000
Morphine	50	1	140
Fentanyl	85	1	153

≥30,000-fold selectivity for κ-receptors versus μ- or δ- receptors

- Novel, first-in-class "kappa" receptor agonist (IP: COM 2027)
- Peripherally restricted – hydrophilic, tetra-peptidic scaffold
- Designed to function **without traditional opioid side effects** ("mu" agonist effects)

CARA

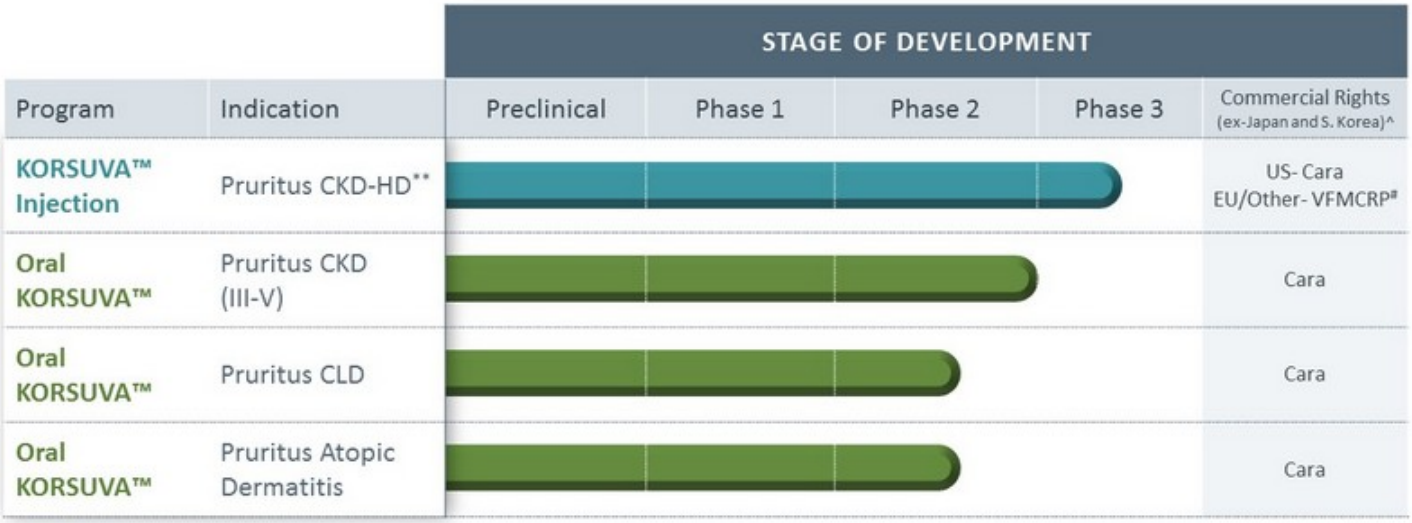
KORSUVA™ Directly Blocks Pruritus Sensory Neurons



5 Source: Adapted from Pflugers Arch . 2013 December; 465(12): . doi:10.1007/s00424-013-1284-2

CARA

Development Pipeline



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

^ Commercialization rights to CR845 in defined indications - Japan: Maruishi Pharma; South Korea: CKD Pharma
** Breakthrough Designation for IV CR845 for Pruritus CKD-HD
# VFMCRP and Cara have rights to promote in Fresenius Medical Care dialysis clinics in the US under a profit share agreement

CKD-HD: Chronic Kidney Disease - Hemodialysis; **CLD**: Chronic Liver Disease

KORSUVA™ Injection for Dialysis Patients

CARA THERAPEUTICS

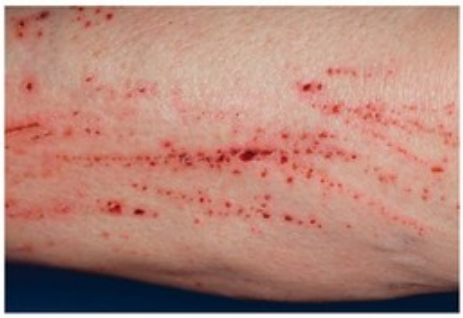
CKD-associated Pruritus (CKD-aP) in Hemodialysis (HD) Patients

Serious itching condition directly related to chronic kidney failure

- Reported by ~60% to 70% of HD patients
- In contrast to dermatological pruritus, primary skin lesions are not observed

Itching severity associated with worsening Quality of Life (QoL) [emotional and physical]

- Sleep disturbance, depressed mood, anxiety, socialization
- Increased mortality risk



Mettang T, Kremer AE. *Kidney Int.* 2015

Pisoni RL et al. *Nephrol Dial Transplant* 2006; Rayner et al., Clin J Am Soc Nephrol 2017; Fishbane et al. *NDT* 2001; Ramakrishnan et al. *International Journal of Nephrology and Renovascular Disease* 2014; Narita et al 2006; Shirazian et al. Int J Nephrol Renovasc Dis. 2017; Mathur et al., Clin J Am Soc Nephrol 2010; Szepietowski et al., Neprol Dial Transplant 2004;

US Market Opportunity for KORSUVA™ Injection in Dialysis Patients

60%
of ESRD patients have pruritus[2,3]

>500K
patients on dialysis

~40%
have moderate to severe pruritus

Per NKF, >500K patients undergoing dialysis in the US[1]

- ~60% have some form of pruritus[2,3]
- Itching severity associated with worsening Quality of Life (QoL) Sleep disturbance, depressed mood/anxiety, socialization
- Increased mortality risk

KORSUVA™ granted Breakthrough Therapy Designation for CKD-aP

- Significant unmet need
- No FDA approved therapies

Per Nov. 2018 CMS rule: within the ESRD Prospective Payment System all new dialysis drugs eligible for reimbursement at ASP for 2 yrs under TDAPA, effective Jan. 1, 2020[4]

1. National Kidney Foundation
2. Pisoni RL, Wikstrom B, Elder SJ, et al. Nephrol Dial Transplant. 2006;21:3495-3505.
3. Ramakrishnan et al. International Journal of Nephrology and Renovascular Disease. 2014:7 1–12
4. https://www.govinfo.gov/content/pkg/FR-2018-11-14/pdf/2018-24238.pdf

CARA

KORSUVA Injection in CKD-HD: Phase 3 Program

KALM-1 trial (US):
Data Readout

- Met Primary and all Secondary Endpoints

The NEW ENGLAND JOURNAL of MEDICINE

KALM-2 trial (Global):
Fully Enrolled: Dec. 2019

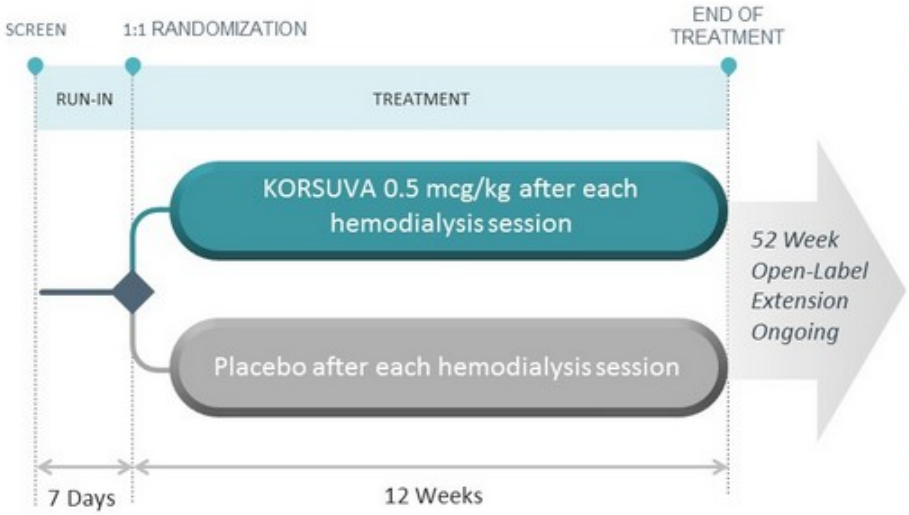
- Includes centers in the US, Europe and Asia Pac regions
- Topline Data: Q2, 2020

Open label safety studies:
Ongoing

- > 1500 total exposures
- > 500 at 6 months
- > 200 at 1 year

CARA

KALM-1 Phase 3 Pivotal Study Design



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

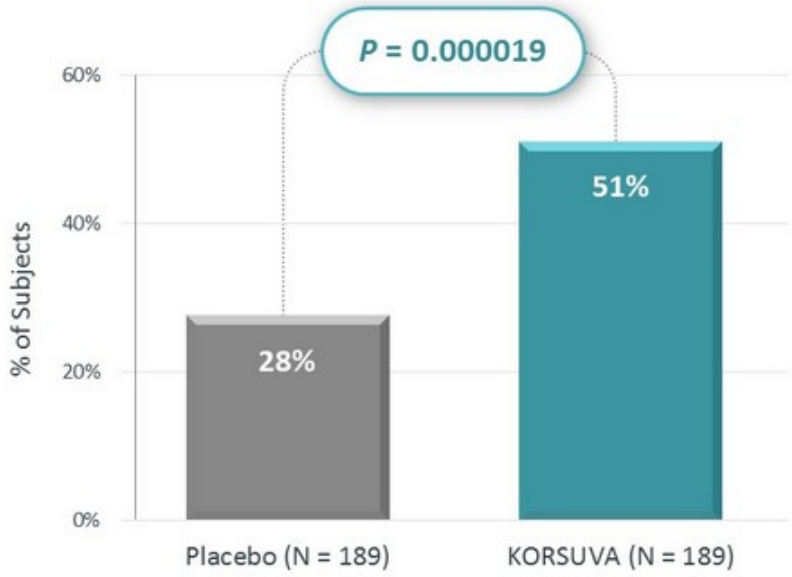
- Proportion of subjects achieving ≥4 point improvement in WI-NRS
- Change from baseline in itch-related Quality of Life as measured by 5-D Itch and Skindex-10 questionnaires

CARA

KALM-1 Phase 3 Primary Endpoint: ≥3 point improvement WI-NRS

TOP-LINE RESULTS:

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



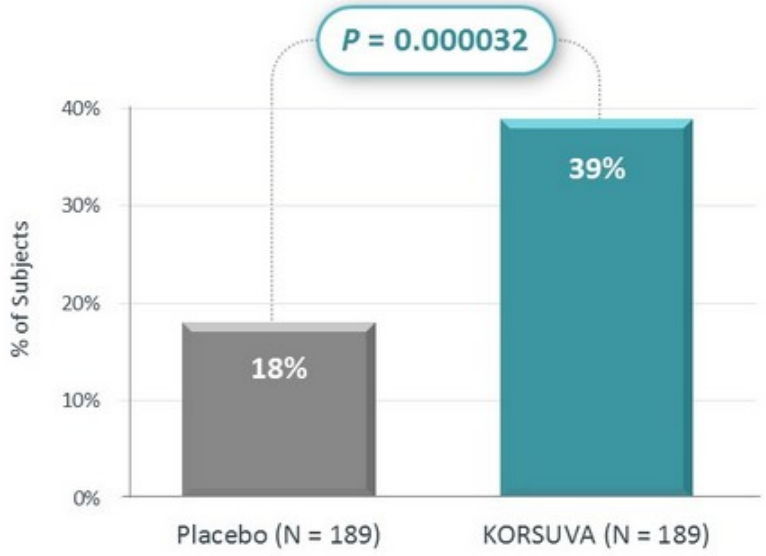
Estimated percentage & P-value based on a logistic regression model with terms for treatment group, baseline WI-NRS score, and strata
Missing data imputed using multiple imputation (MI) under missing at random (MAR) assumption
Odd Ratio: 2.72

CARA

Secondary Endpoint: ≥4 point improvement WI-NRS

TOP-LINE RESULTS:

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

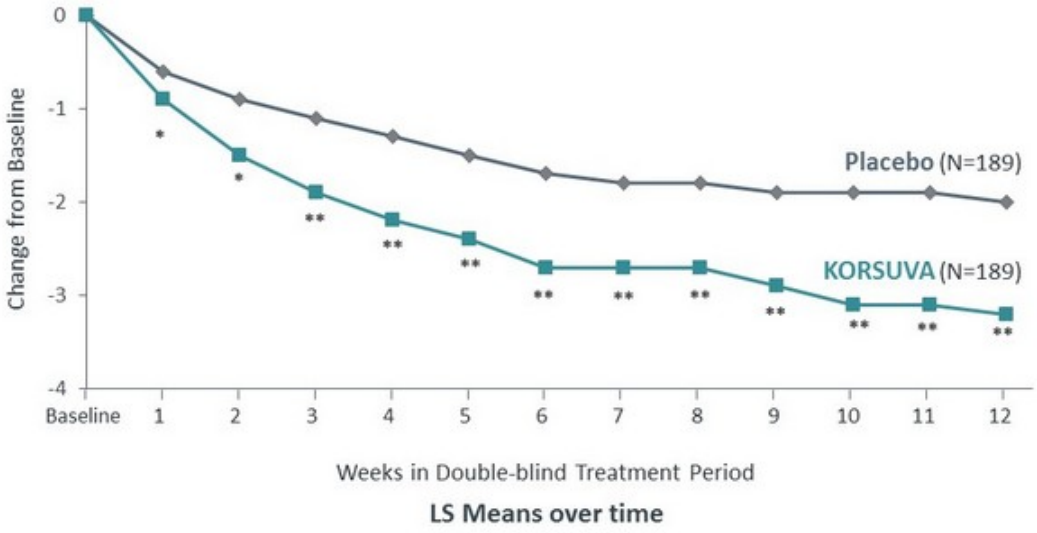


Estimated percentage & P-value based on a logistic regression model with terms for treatment group, baseline WI-NRS score, and strata
Missing data imputed using multiple imputation MI) under missing at random (MAR) assumption
Odd Ratio: 2.9

CARA

Change in Worst Itching Intensity NRS Over Time

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



LS Means over time

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

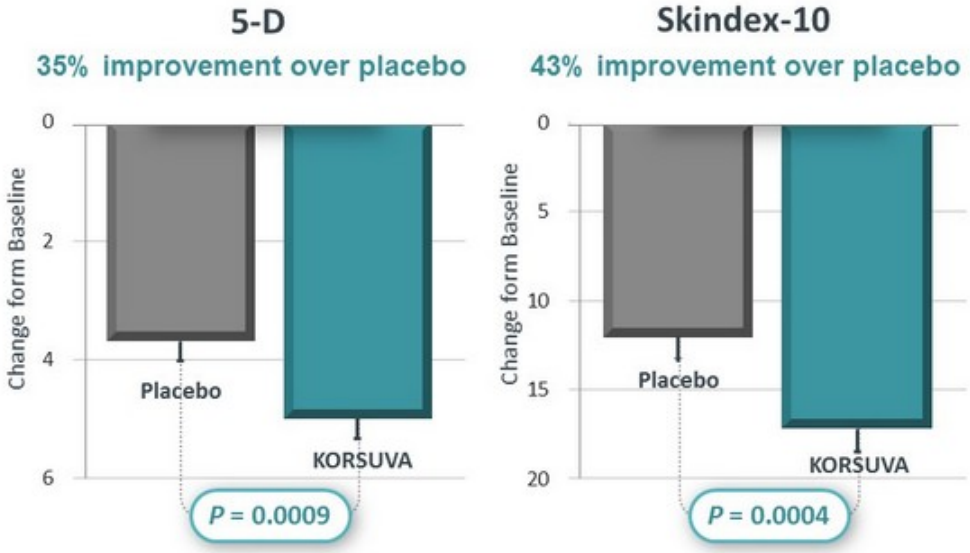
LS Means from MMRM with terms for treatment group, week, week by treatment interaction, baseline score and strata
Missing data imputed using multiple imputation (MI) under missing at random (MAR) assumption

CARA

Secondary Endpoints: 5D-Itch and Skindex-10

TOP-LINE RESULTS:

Significant improvements in itch-related QoL measures



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

CARA

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)

CARA

Vifor Fresenius Medical Care Renal Pharma (VFMCRP)

Ex-US License Agreement:

KORSUVA INJECTION (difelikefalin) for the prevention, inhibition or treatment of itch associated with pruritus in hemodialysis/ peritoneal dialysis patients

Financials

- $70M upfront
  ($50M cash + $20M in Cara equity at premium)
- Up to $470 million
  Regulatory and commercial milestones
- Tiered double-digit royalty based on net sales in licensed territory

Licensed Territory

- Worldwide, excluding US, Japan & South Korea

VFMCRP & Cara co-promotion and profit share arrangement in US Fresenius Medical Care clinics

- Cara has sole promotion and profit retention in all non-Fresenius US dialysis clinics

CARA THERAPEUTICS

Oral KORSUVA™ Development Programs

Development Programs for Oral KORSUVA™

Phase 2 Trial Complete
CKD-aP (Stage III-V)

~25 to 30% experience pruritus

Phase 2 Trial
Atopic Dermatitis

~87% to 100% experience pruritus

Phase 2 Trial
Chronic Liver Disease Pruritus

~30% experience pruritus

CARA

Oral KORSUVA™ for CKD-associated Pruritus

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 significant under-recognized US public health issue

- ~30 million people affected

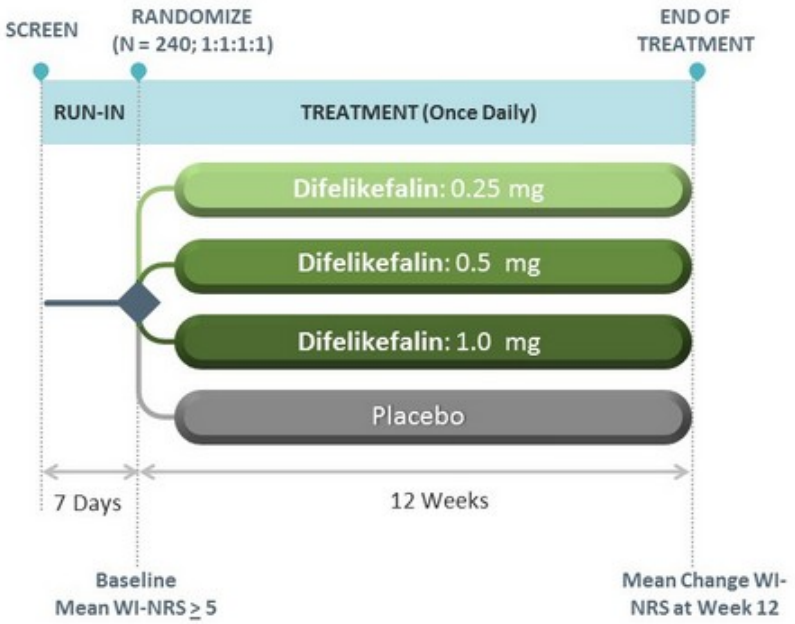
No FDA approved therapies – large unmet medical need

- 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

CARA

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



Endpoints: Week 12

Primary

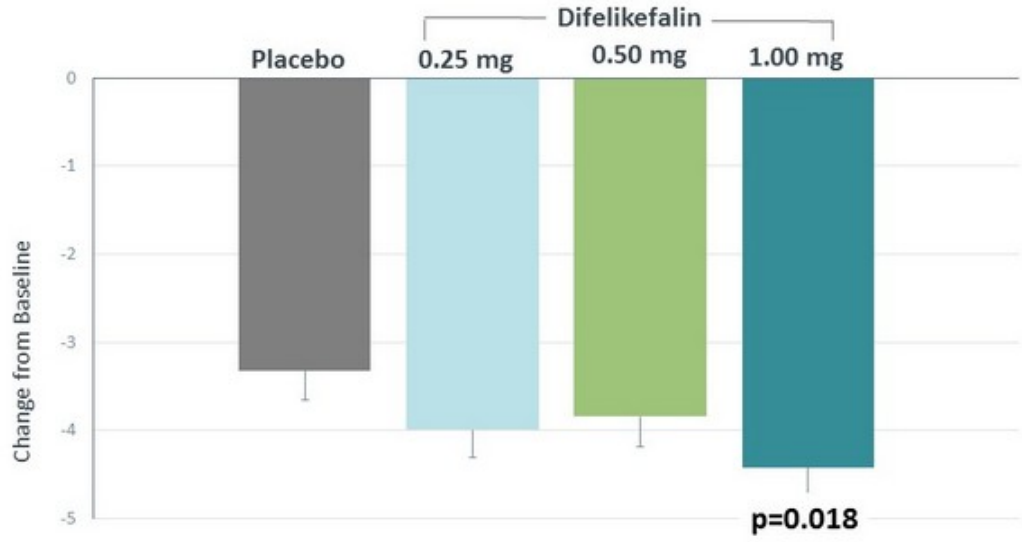
- Change from baseline in weekly mean of daily Worst Itching Intensity NRS (WI-NRS) score

Secondary & Additional

- 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
- WI-NRS complete responder; patient global impression of change

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

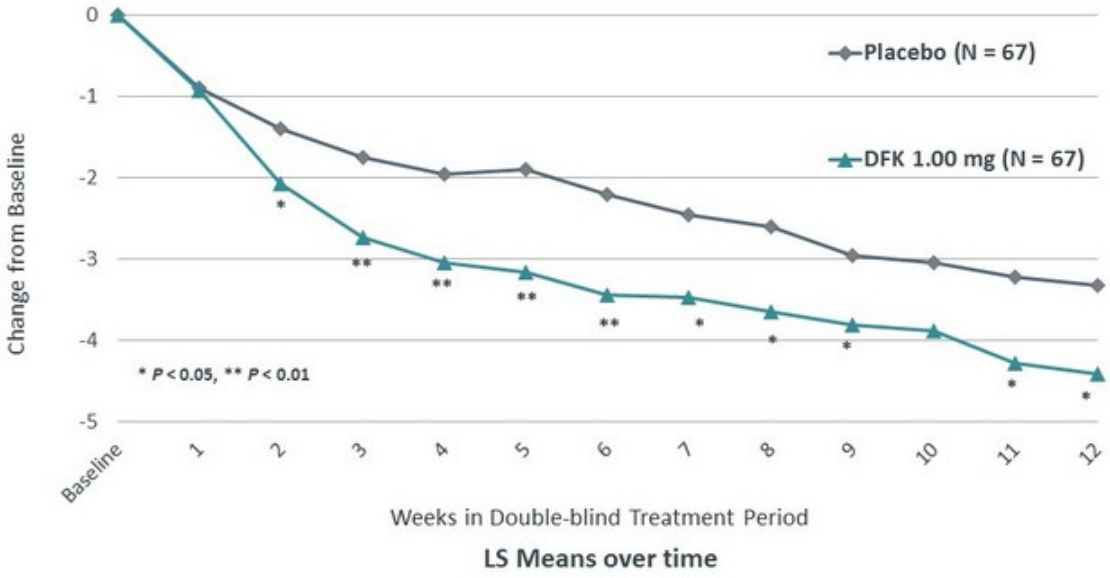


LS Mean from MMRM with terms for treatment group, week, week by treatment interaction as fixed effects; baseline score and strata as covariates; patient as a repeated measures
Missing data imputed using multiple imputation (MI) under missing at random (MAR) assumption

CARA

Change in Worst Itching Intensity NRS Over Time

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

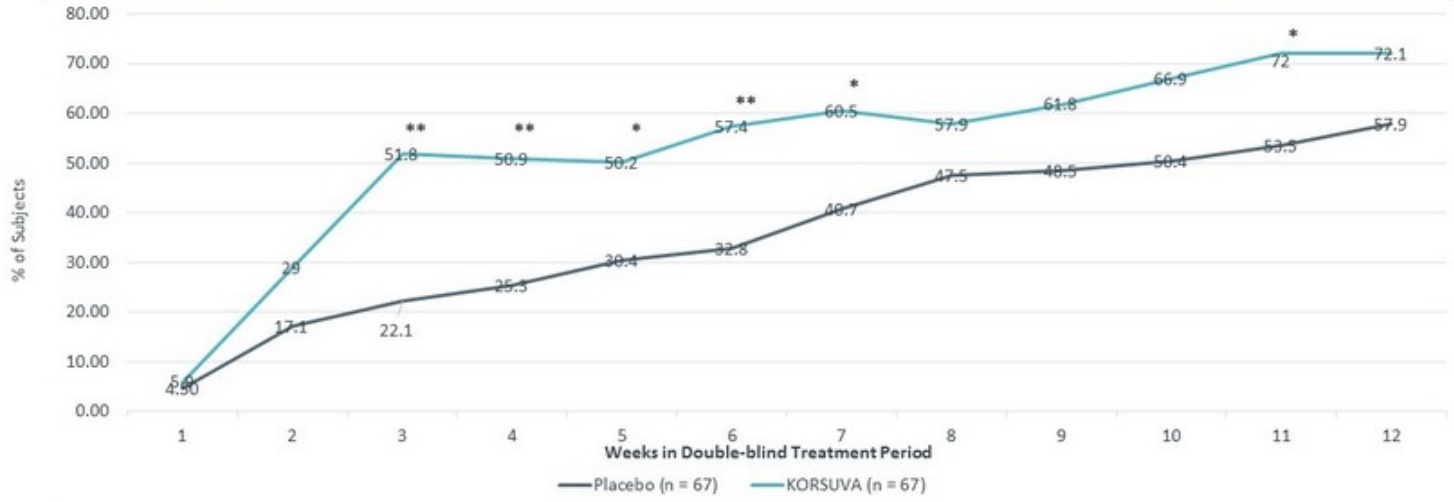


LS Mean from MMRM with terms for treatment group, week, week by treatment interaction as fixed effects; baseline score and strata as covariates; patient as a repeated measures
Missing data imputed using multiple imputation (MI) under missing at random (MAR) assumption

CARA

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

72% of KORSUVA 1.0 mg subjects experienced ≥ 3 point improvement from baseline at week 12



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

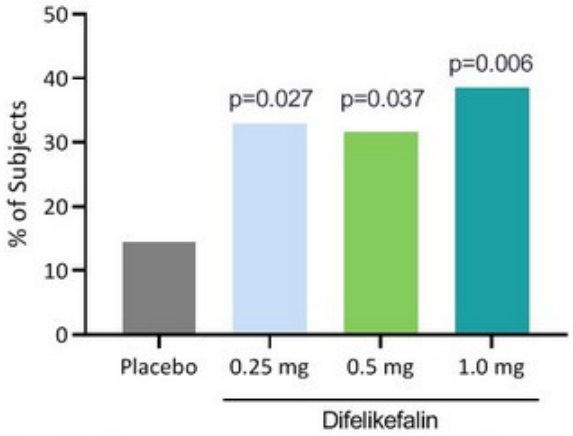
Estimated percentage & P-value based on a logistic regression model with terms for treatment group, baseline WI-NRS score, and renal disease status

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

CARA

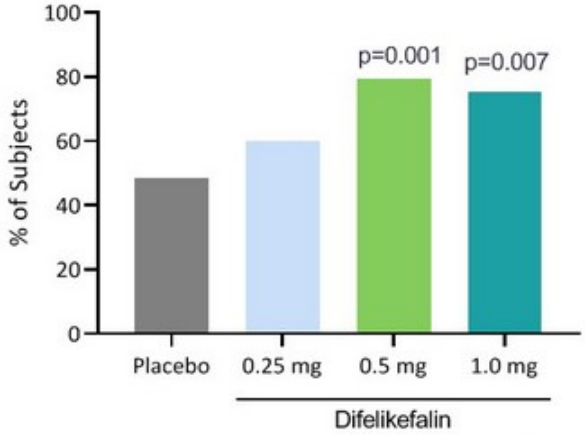
Additional Pre-specified Endpoints

NRS Complete Responder*



*80% of NRS scores at Week 12 equal to 0 or 1.

Patient Global Impression of Change#



'Much Improved' or 'Very Much Improved' Week 12.

Estimated percentage and P-values 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

CARA

Oral KORSUVA™ for CKD-aP: Summary & Next Steps

- Oral KORSUVA met the primary endpoint:
  1mg dose identified for advancement to Phase 3

- Oral KORSUVA was generally well-tolerated:
  safety profile similar to Phase 3 KORSUVA Injection studies

- Projected End-of-Phase 2 FDA meeting/Phase 3 start: 2H,'20

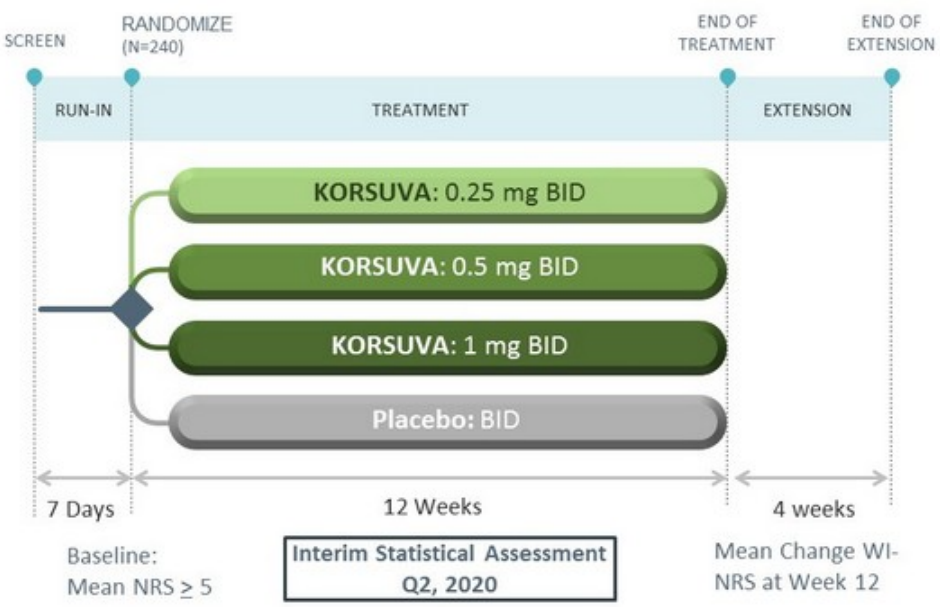
CARA

Oral KORSUVA™: Additional Pruritus Development Programs

Atopic Dermatitis
Chronic Liver Disease

CARA THERAPEUTICS

Atopic Dermatitis Associated Pruritus: Phase 2 Trial Ongoing



Study

320 adult patients with AD (80/arm) and moderate to severe pruritus

Primary Endpoint:

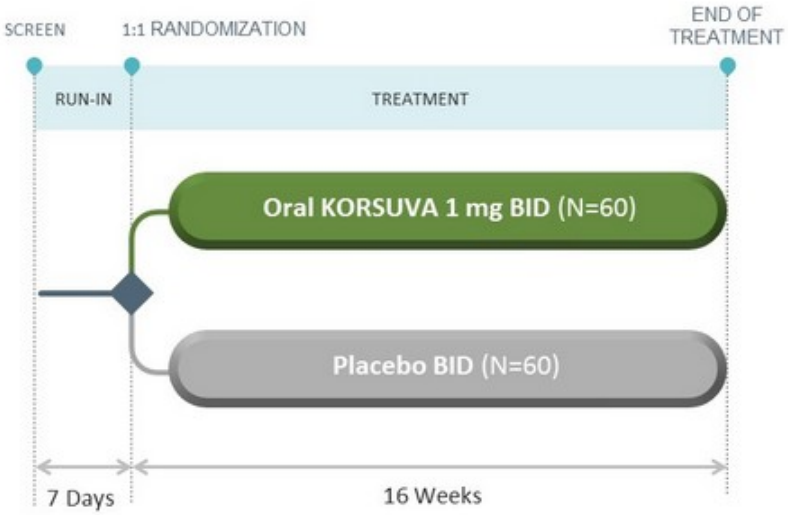
- Change from baseline in the weekly mean of the daily 24-hour WI-NRS score at Week 12

Secondary Endpoints:

- Responder analysis (Week 12): Change from baseline in I-NRS score of ≥4 points
- Change in itch related QoL: Skindex-10, 5-D Itch scales & Sleep Quality Assessment at week 12
-

CARA

Pruritus Associated with Primary Biliary Cholangitis (PBC): Phase 2



Study

A 16-week, double blind, randomized, PBO-controlled study in PBC patients with moderate to severe pruritus

Primary Endpoint:

- Change from baseline in the weekly mean of the daily 24-hour WI-NRS score at week 16

Secondary Endpoints:

- Change in itch related QoL: Skindex-10 & 5-D Itch scales at week 16
- Responder analysis (Week 16): Change from baseline in weekly main of daily worst NRS score of ≥3 points

CARA

Projected Clinical Milestones –2020

	Pruritus / KORSUVA™ Injection	Pruritus / Oral KORSUVA™
2Q,2020	**Top-line data: KALM-2 Ph 3 trial** (CKD-aP in dialysis pts)	**Interim statistical analysis Phase 2 Atopic Dermatitis**
2H,2020	**NDA submission**	**Top-line data Ph2 trials:** Atopic Dermatitis Chronic Liver Disease
2H,2020		**Phase 3 initiation CKD-aP** (Stage III-V CKD)

CARA

Financial Highlights

Cash/marketable securities
(SEPTEMBER 30, 2019)
$249.1M

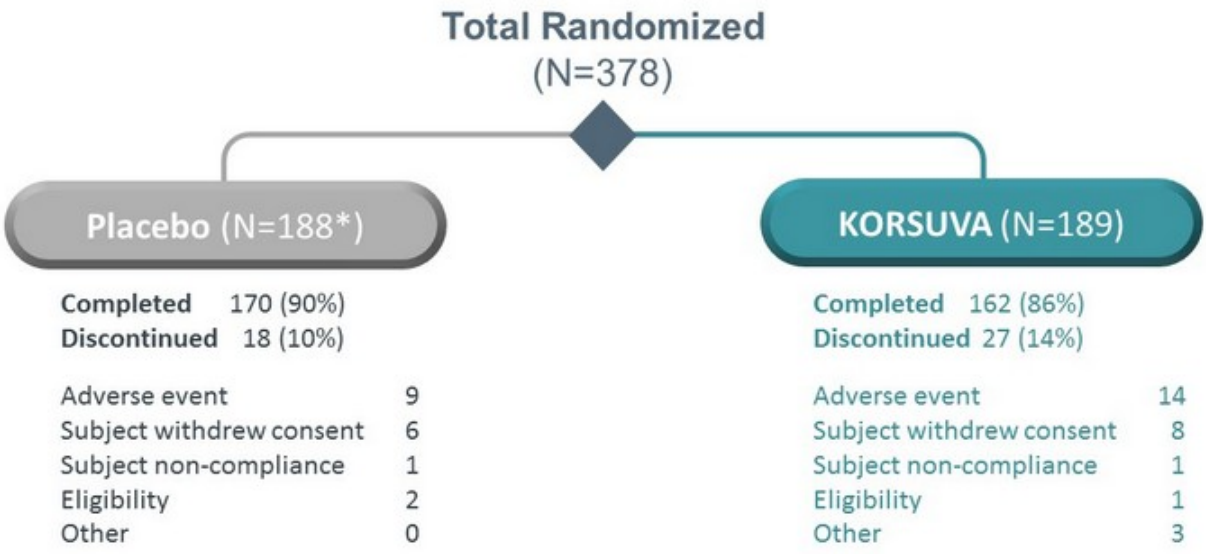
Net loss
(SEPTEMBER 30, 2019)
($32.8M)

Shares outstanding
(POST-JULY'19 OFFERING)
~46.4M

CARA

Appendix

KALM-1: Patient Disposition



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

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)

CARA

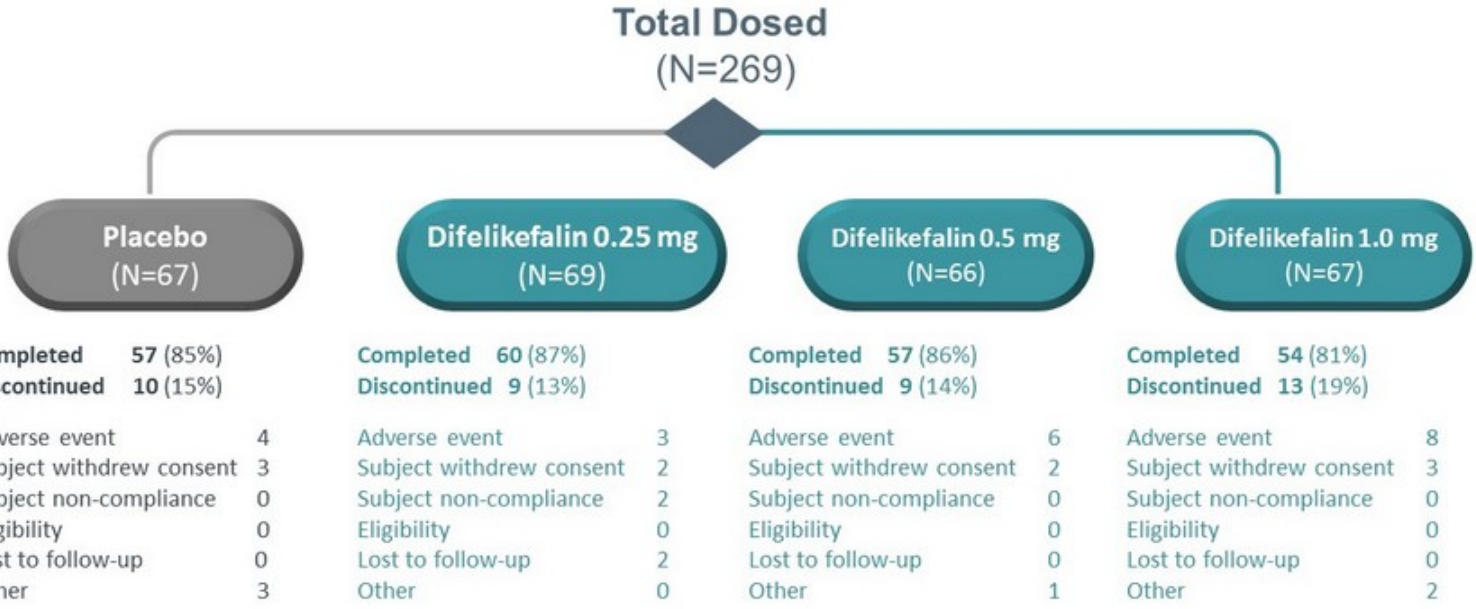
KALM-1 Phase 3 Pivotal Top-line Results Summary

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

CARA

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%)	**Completed**	**60** (87%)	**Completed**	**57** (86%)	**Completed**	**54** (81%)
Discontinued	**10** (15%)	**Discontinued**	**9** (13%)	**Discontinued**	**9** (14%)	**Discontinued**	**13** (19%)
Adverse event	4	Adverse event	3	Adverse event	6	Adverse event	8
Subject withdrew consent	3	Subject withdrew consent	2	Subject withdrew consent	2	Subject withdrew consent	3
Subject non-compliance	0	Subject non-compliance	2	Subject non-compliance	0	Subject non-compliance	0
Eligibility	0	Eligibility	0	Eligibility	0	Eligibility	0
Lost to follow-up	0	Lost to follow-up	2	Lost to follow-up	0	Lost to follow-up	0
Other	3	Other	0	Other	1	Other	2

CARA

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)

CARA

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)

CARA

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

N (%)	Placebo	Difelikefalin		
	N = 67	0.25 mg N = 69	0.5 mg N = 66	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)
Gastrooesophageal reflux disease	0	0	4 (6.1)	0

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

CARA