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 11, 2016

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.)**

1 Parrott Drive **Shelton, Connecticut**	**06484**
(Address of principal executive offices)	**(Zip Code)**

Registrant's telephone number, including area code (203) 567-1500

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))

Item 7.01. Regulation FD Disclosure.

A copy of the investor presentation that Cara Therapeutics, Inc. plans to use in conjunction with meetings, beginning on January 11, 2016, during the J.P. Morgan Healthcare Conference is furnished as Exhibit 99.1 to this Form 8-K and is incorporated herein by reference. The information contained in the presentation furnished as Exhibit 99.1 shall not be deemed "filed" for purposes of Section 18 of the Securities Exchange Act of 1934, as amended, or the Exchange Act, and is not incorporated by reference into any of the Company's filings under the Securities Act of 1933, as amended, or the Exchange Act, whether made before or after the date hereof, except as shall be expressly set forth by specific reference in any such filing.

Item 9.01. Financial Statements and Exhibits.

(d) Exhibits

Exhibit No.	Description
99.1	Cara Therapeutics, Inc. Corporate Presentation January, 2016.

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/ JOSEF SCHOELL
Josef Schoell
Chief Financial Officer
(Principal Financial and Accounting Officer)

Date: January 11, 2016

Exhibit 99.1

Novel Peripheral Kappa Opioid Product Candidates: Efficacy Without Opioid Side Effects

JPM Healthcare Conference

January, 2016

CARA THERAPEUTICS

Forward Looking Statements

This presentation contains certain forward-looking statements that involve risks and uncertainties that could cause actual results to be materially different from historical results or from any future results expressed or implied by such forward-looking statements. In some cases, you can identify forward-looking statements by the words “anticipate,” “believe,” “continue,” “estimate,” “expect,” “objective,” “ongoing,” “plan,” “propose,” “potential,” or “up-coming” and/or the negative of these terms, or other comparable terminology intended to identify statements about the future. Forward-looking statements in this presentation include, among other things, statements about: the success and timing of our clinical trials, including our pivotal clinical program for I.V. CR845 in acute pain; our plans for future clinical development of I.V. CR845 for uremic pruritus; our plans to develop and commercialize I.V. CR845 and our other product candidates, including Oral CR845; the size of the potential markets for pain management, including the postoperative and chronic pain market and the uremic pruritus market; the trial design for future clinical trials, including the proposed Phase 2b oral clinical trial for CR845 and projected clinical milestones for I.V. CR845 and Oral CR845.

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 31st, 2014 and Quarterly Report on Form 10-Q for the quarter ended June 30, 2015, 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. We undertake 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.

U.S. Mu-Opioid Market Size and Adverse Events

Significant Market with Significant Concerns		
	Post-Operative Pain	**Outpatient Pain (Acute and Chronic)**
Market Size		
Number of Patients / TRx	60 MM[1]	457 MM (TRx)[2]
Opioids Patients /TRx	234 MM doses[6]	267 MM (TRx)[2]
Market Concerns		
Incidence of N/V	30-50%[3]	30-40%[3]
Respiratory Depression	0.5-2.0%[5]	N/A
Deaths (overdose)	N/A	16,000[4]

1. CDC National Hospital Discharge Survey 2010 and National Health Statistics Reports 2006. Factored for moderate to severe pain (71%).
2. IMS NPA Audit from January 2014 to December 2014.
3. Package Inserts from commonly prescribed opioids (OxyContin, Nucynta/Nucynta ER, Zohyrdo, Opana/Opana ER, Embeda, Sublimaze, Dilaudid)
4. Centers for Disease Control and Prevention. National Vital Statistics System mortality data. (2015) Available from URL: http://www.cdc.gov/nchs/deaths.htm.
5. Overdyk FJ. Postoperative opioids remain a serious patient safety threat. *Anesthesiology* 7 2010, Vol.113, 259-260
6. IMS NSP Audit January 2014 to December 2014

CARA THERAPEUTICS

Cara: Developing First-in-Class Peripheral Opioid

- **Novel opioids without traditional opioid side effects**
  - Kappa opioid agonists with unique pharmacology and chemotype
  - NCEs with patent protection through at least 2027
  - MOA: Anti-Nociceptive/Anti-Inflammatory & Anti-Pruritic
- **Lead candidate, I.V. CR845 - Phase 3 Program post-op pain 9/15**
  - Positive results in three Phase 2 trials in over 250 patients
  - Statistically significant reductions in pain and opioid-related adverse events across all three trials
- **Successful Phase 2 Trial of I.V. CR845 in Uremic Pruritus**
  - Primary & Secondary Endpoints: Reduction in worst itch & improved QoL
  - Completed FDA meeting Q4, 2015
- **Completed Phase 2a Osteoarthritis Trial Q4, 2015**
- **IPO completed 2/5/2014 – $56M: Follow-On Offering 7/29/15 - $75M**

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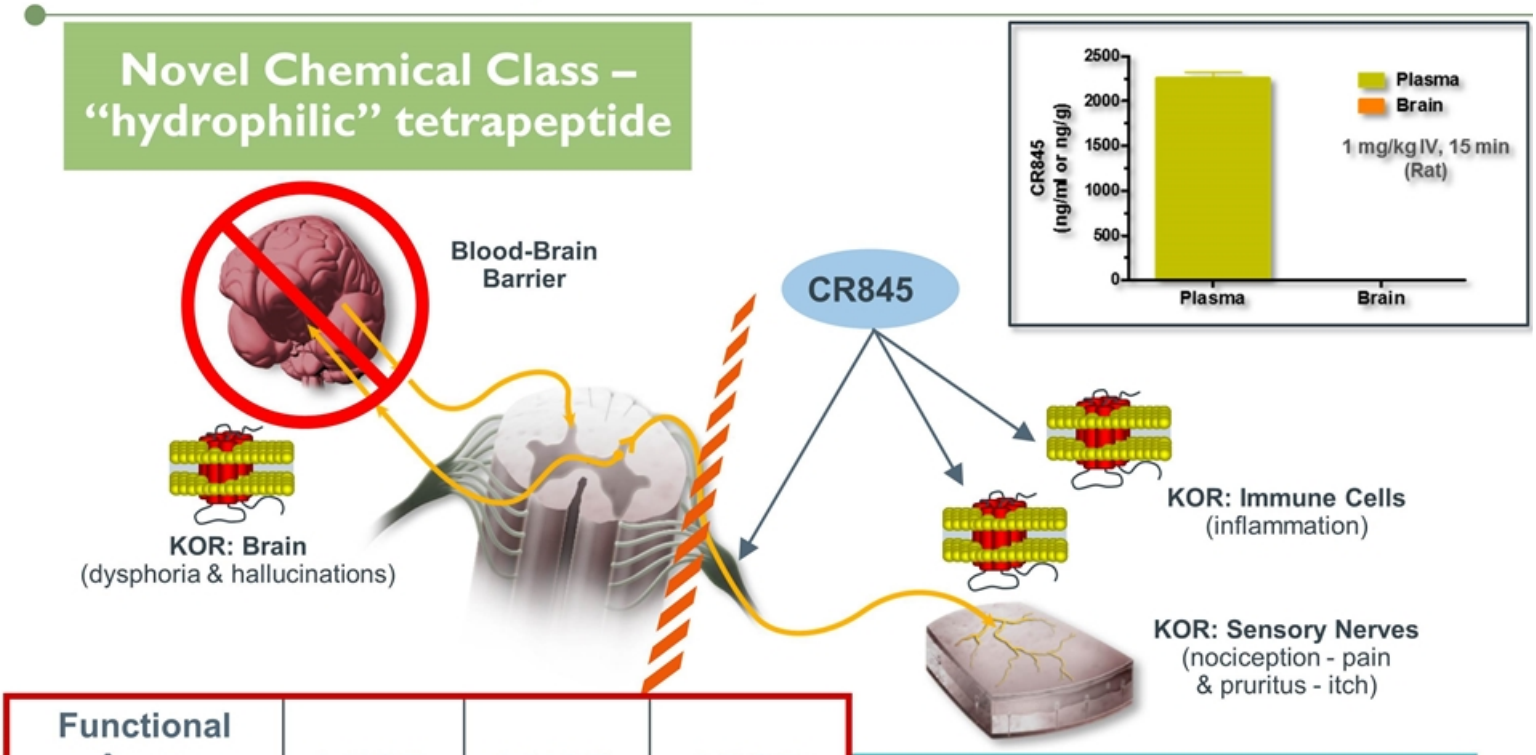
CR845 Has A Unique "Peripheral" Mechanism of Action

Novel Chemical Class – "hydrophilic" tetrapeptide



Functional Assay (EC_{50}, nM)	hKOR	hMOR	hDOR
CR845	0.16	>10,000	>10,000

Dual Antinociceptive-Anti-Inflammatory Action

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CR845 Pipeline: Pursuing 3 Possible NDA Paths

I.V. CR845 – Acute Post-Op Pain

- Initiated Pivotal P3 Program – Q3, 2015

I.V. CR845 – Uremic Pruritus

- Completed FDA Meeting – Q4, 2015

Oral CR845 – Acute/Chronic Pain

- Completed Phase 2a Trial – Q4, 2015

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Osteoarthritis Phase 2a Trial
CLIN2001-PO: Protocol Overview

Main Study Objective

- Assess the safety and tolerability of orally-administered CR845 in patients with osteoarthritis (OA) of the hip or knee
- Characterize the PK profile of orally-administered CR845 with b.i.d. dosing
- Explore the effectiveness of orally-administered CR845 in this patient population

Study Design

- Single-Blind, Multiple Ascending-Dose Phase 2a Study, with repeat doses of CR845 over a two-week period in patients with moderate-to-severe pain (≥ 4) associated with OA. Four treatment arms: oral b.i.d. doses: 0.25mg 0.5mg, 1mg & 5mg tablets

Patients

- 80 male and female patients – 20/treatment arm (baseline NRS ≥ 4), 5 U.S. sites
- Mean patient duration of OA at Screening – 9.4 years

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Study CR845-CLIN2001-PO

Patient Demographics

	Cohort 1 0.25mg (n= 20)	Cohort 2 0.5mg (n= 21)	Cohort 3 1.0mg (n= 20)	Cohort 4 5.0mg (n= 20)
Gender				
Male	10 (50%)	14 (66.7%)	8 (40%)	11 (55%)
Female	10 (50%)	7 (33.3%)	12(60%)	9 (45%)
Age, mean (range)	63.2 (46-77)	63.3 (32-80)	62.9 (38-81)	63.1 (40-79)
Race				
Black	5 (25%)	4 (19%)	1 (5%)	5 (25%)
White	15 (75%)	17 (81%)	19 (95%)	15 (75%)
Ethnicity				
Hispanic or Latino	0 (0%)	1 (4.8%)	1 (5%)	0 (0%)

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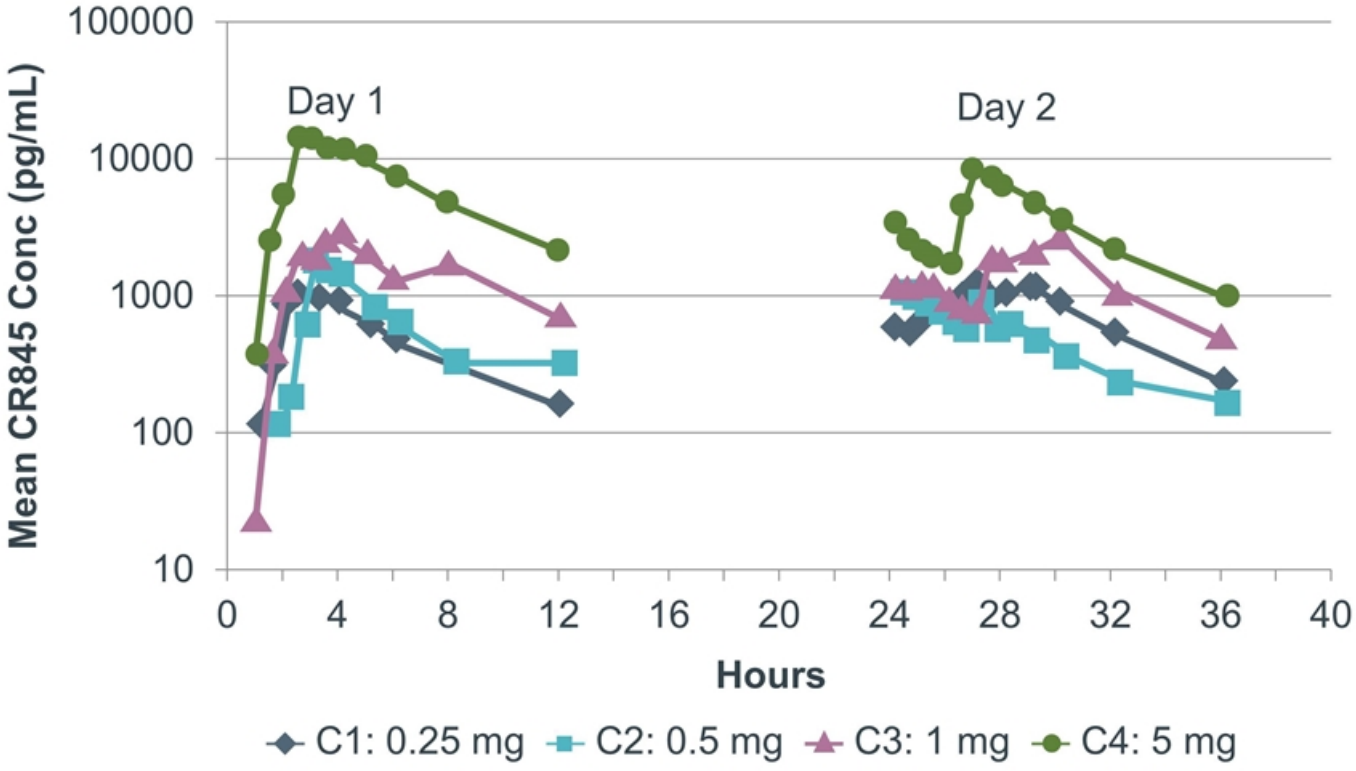
Study CR845-CLIN2001-PO

CR845 Plasma Concentration Over Time



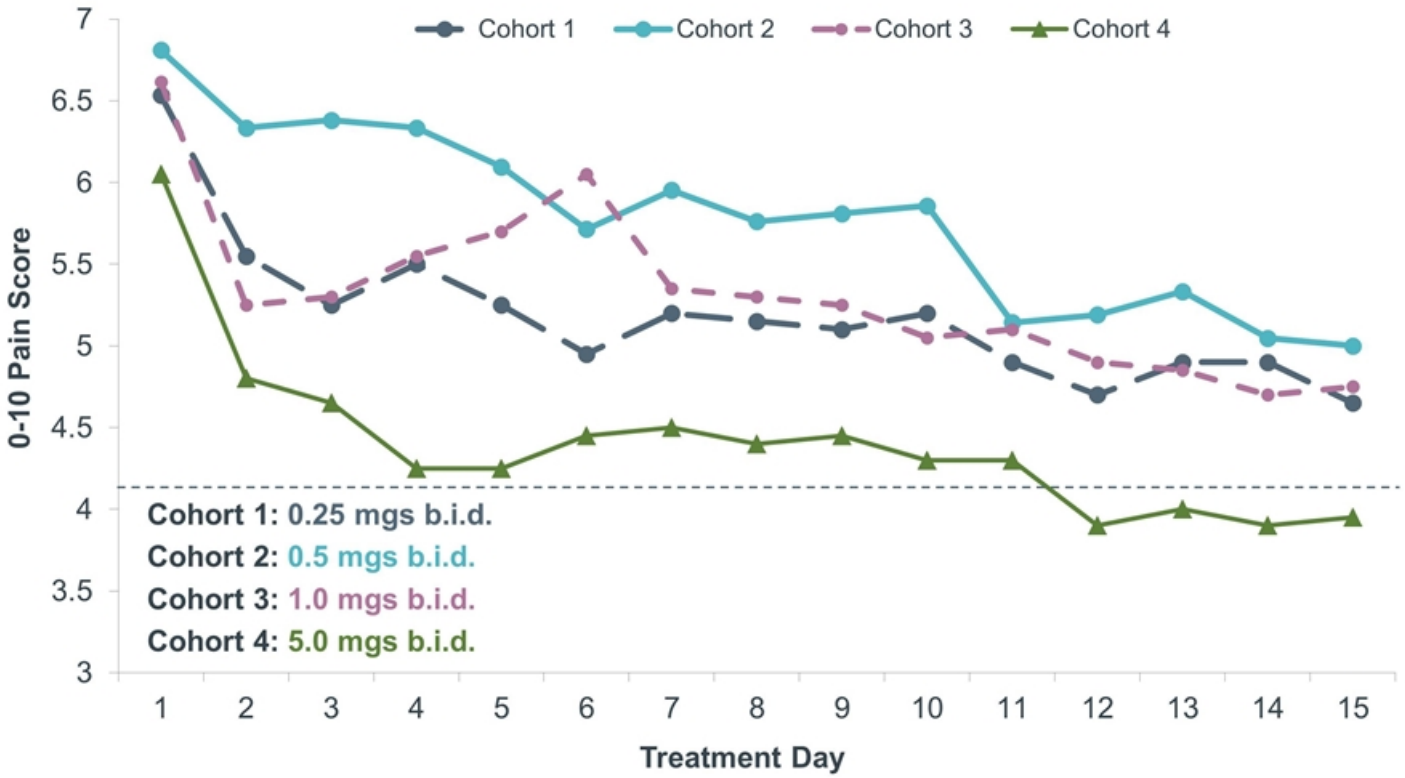
Study CR845-CLIN2001-PO

Safety/Tolerability Summary

- 65% of reported adverse events were characterized as mild and the remainder of events were moderate. No severe AEs were reported
- Adverse events appear to be dose-related: 20% in high (5mg) group
- Treatment-related AEs with >5% incidence:
  - Dizziness (7%)
  - Headache(6%)
- One study SAE – status epilepticus (non-drug related)

Study CR845-CLIN2001-PO

Mean NRS Score by Cohort and Treatment Day – LOCF



11 LOCF analysis

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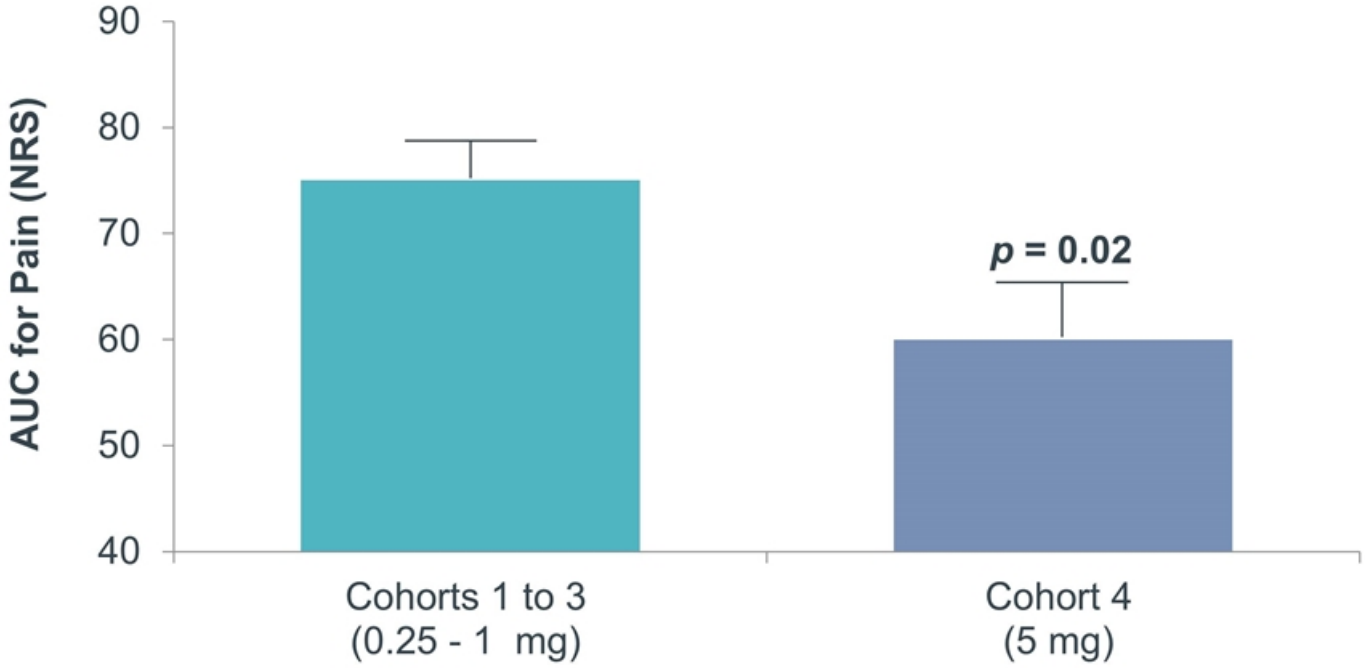
Study CR845-CLIN2001-PO

Area Under the Curve (AUC) for Pain NRS: Days 1 to 15



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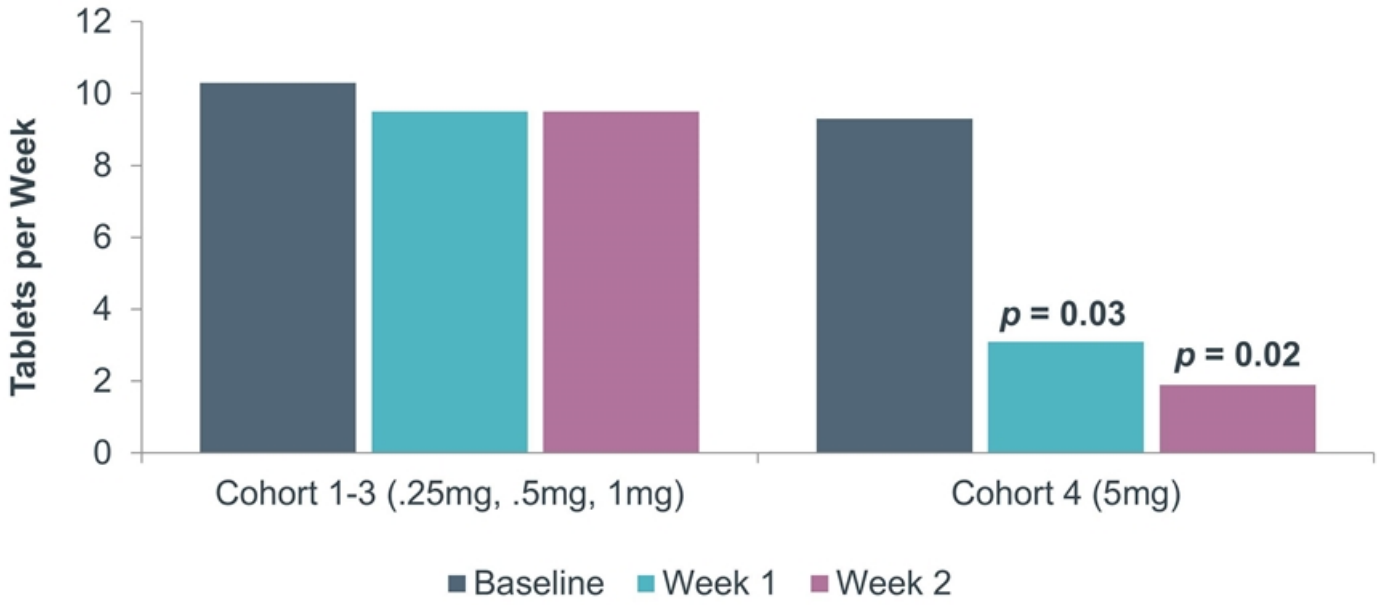
Study CR845-CLIN2001-PO

Rescue Medication Use Over Time



59% of Patients in Cohort 4 (5mg) Did Not Require Any Rescue Medication, Week 2

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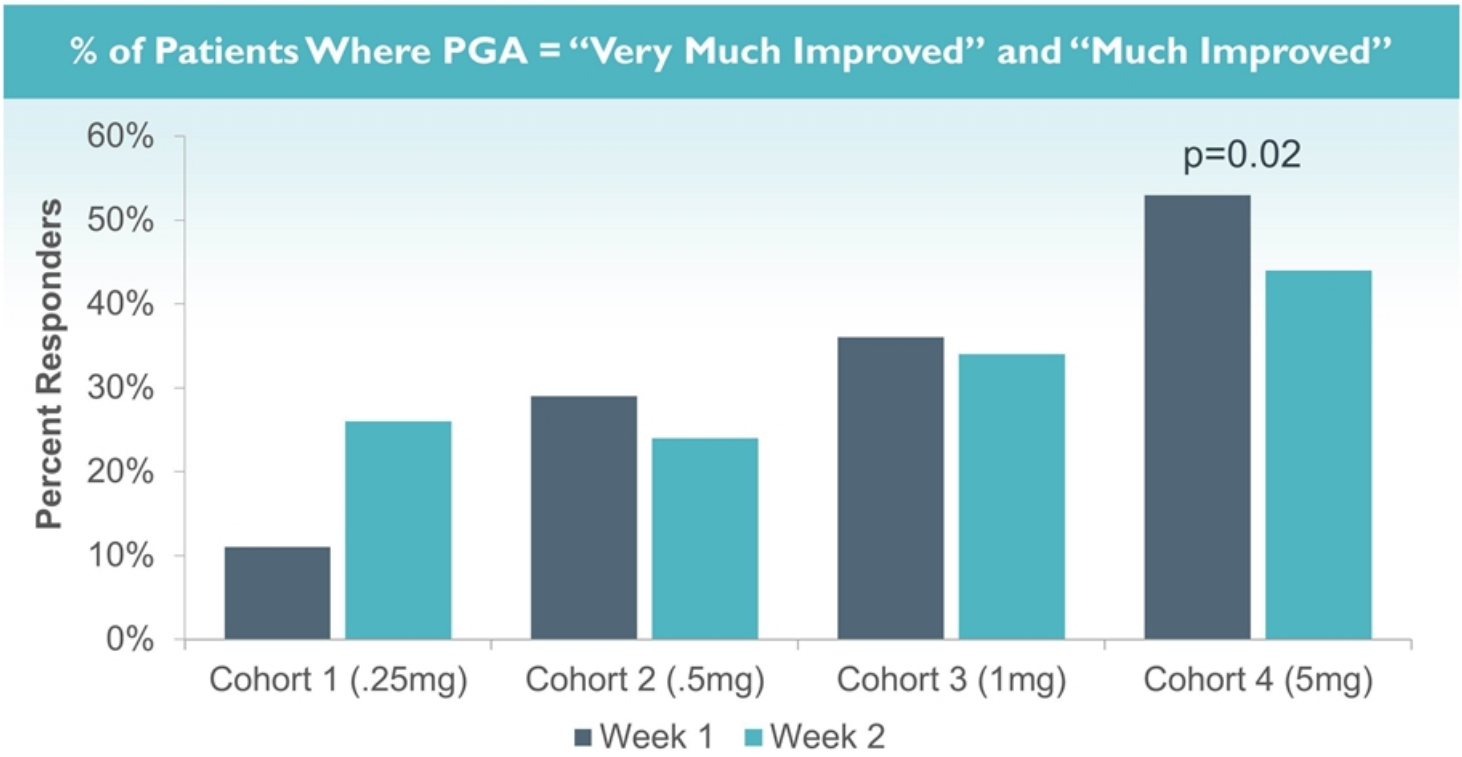
Study CR845-CLIN2001-PO

Patient Global Assessment (PGA)



(Cochran-Mantel-Haenszel test, p=0.02, 2-sided).

Comparative Efficacy in NRS Pain in OA Studies

Drug	Time	Change from BL	% Change from BL
Naproxen[1]	2 weeks	-2.5	35%
Celecoxib[1]	2 weeks	-2.5	35%
Duloxetine[2] (30mg/day)	2 weeks	-1.6	26%
Oxycodone CR[3]	12 weeks	-1.7	26%
CR845 (1mg)	2 weeks	-1.7	26%
CR845 (5mg)	2 weeks	-2.1	34%

[1] Benson, et. al. Treatment of Osteoarthritis with Celecoxib, a Cyclooxygenase-2 Inhibitor: a Randomized Controlled Trial. *Mayo Clin Proc. 1999;74:1095-1105.*

[2] Chappell et. Al., Duloxetine, a centrally acting analgesic, in the treatment of patients with osteoarthritis knee pain: A 13-week, randomized, placebo-controlled trial. *PAIN.* Volume 146, Issue 3, 5 December 2009, Pages 253–260.

[3] Markenson, et. al., Treatment of Persistent Pain Associated With Osteoarthritis With Controlled-Release Oxycodone Tablets in a Randomized Controlled Clinical Trial. *Clin J Pain* Volume 21, Number 6, November/December 2005.

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Planned Osteoarthritis Phase 2b Trial
CLIN2002-PO: Protocol Overview

Main Study Objective

- Assess the efficacy of orally-administered CR845 in patients with osteoarthritis (OA) of the hip or knee
- Assess the safety and tolerability of orally-administered CR845 over 8 week period in patients with osteoarthritis (OA) of the hip or knee

Study Design

- Double-Blind, Multiple Dose Phase 2b, with repeat doses of CR845 over an eight week treatment period in patients with moderate-to-severe pain (≥ 5) associated with OA. Four treatment arms: oral b.i.d. doses: placebo, 3 CR845 tablet strengths

Patients

- ~330 male and female patients – ~15 U.S. sites

CR845 Tablets

Tablet Composition: CR845 tablets (enteric coated)

- CR845 0.1 mg – 20 mg per tablet
- Standard (FDA approved) tablet filler, binder, disintegrant, lubricant
- Two non-listed active excipients: LLC and Citric Acid DC F20*
  - LLC (permeation/absorption enhancer)
    - Type V DMF (preclinical and clinical data, Enteris Biopharma) on file for LLC
  - Citric Acid DC F20 (pH lowering agent, absorption enhancer)
    - Citric Acid (USP/EP) coated with liquid maltodextrin (NF)
    - Food grade product
- Highly stable refrigerated (5ºC, no loss of purity or potency) across all strengths
  - Cara anticipates that a room temperature commercial tablet is feasible (2 year expiration date for strengths ≥ 1 mg)

*Enteris formulation technology

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Post-Operative Pain Is A Large Market

- **Injectable formulation desired**
- **Large market opportunity:**
  - **$9.1 billion of opioid analgesics sales in the U.S. during 2014***

Inadequate Treatment of Post-Surgical Pain**

- Narcotic-based multi-modal analgesia is standard
- 85% of patients report significant post-op pain
  - 75% of pain is moderate-severe
- 79% of patients report AEs from pain medications
  - ***Most AEs opioid-related***

* Source: IMS Health.
** Source: T.J. Gan: The American Society of Regional Anesthesia and Pain Medicine (ASRA), 2012.

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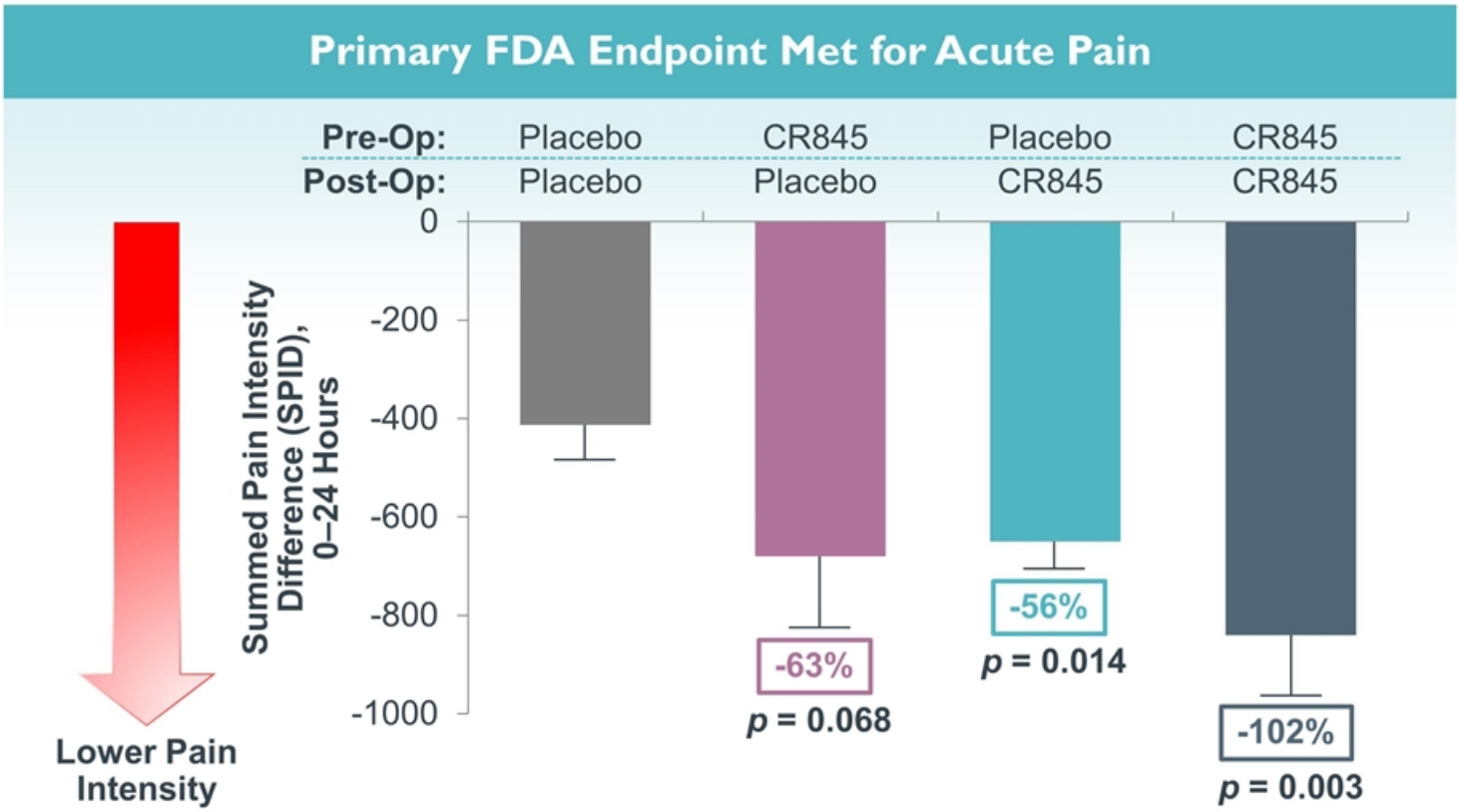
CR845 Phase 2 Hysterectomy Study: Significantly Reduced Post-Op Pain

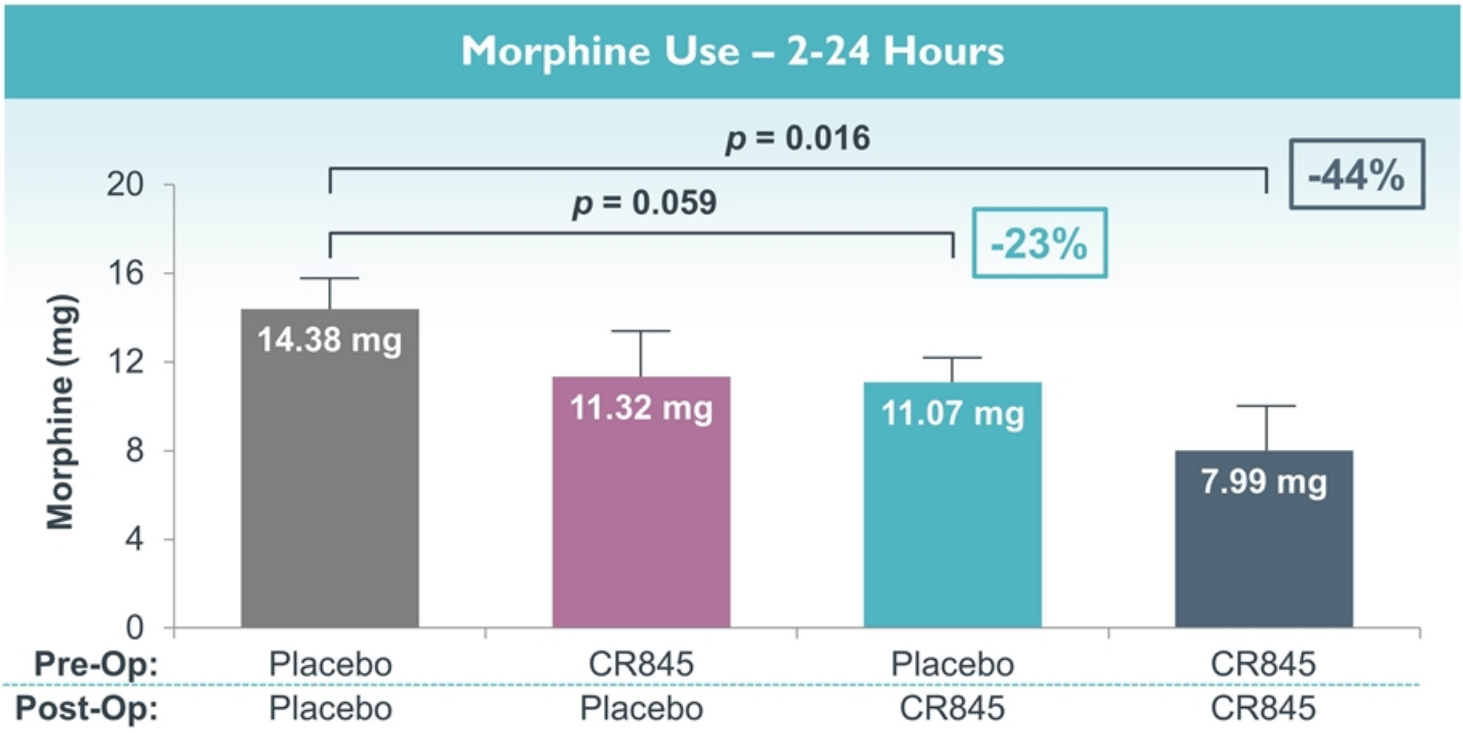
CLIN2002 Trial



$SPID_{0-24}$ (mITT), Mean ± SEM. N = 71, 19, 71 and 20, respectively.

CR845 Phase 2 Hysterectomy Study: Significantly Reduced Post-Op Narcotic Use

CLIN2002 Trial



Mean ± SEM.

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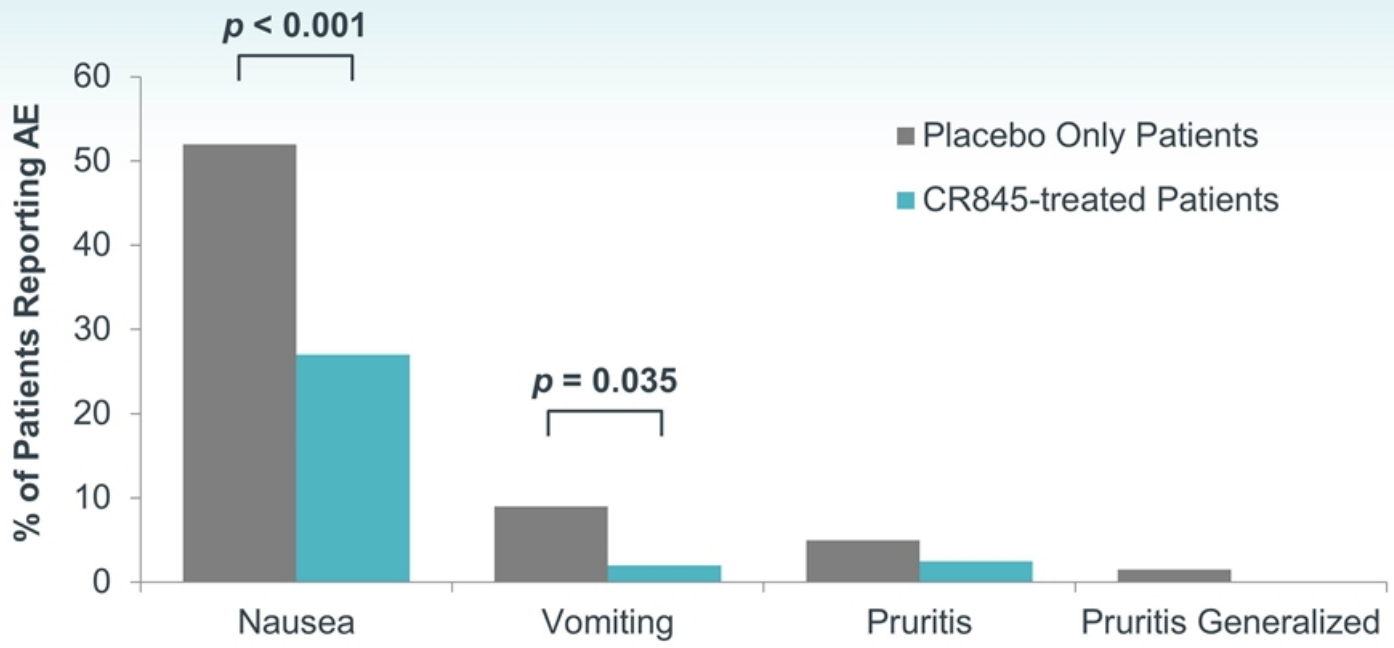
CR845 Phase 2 Hysterectomy Study: Significantly Reduced Opioid-Related Adverse Events

CLIN2002 Trial

Treatment-Emergent AEs Through 24 Hours After First Infusion



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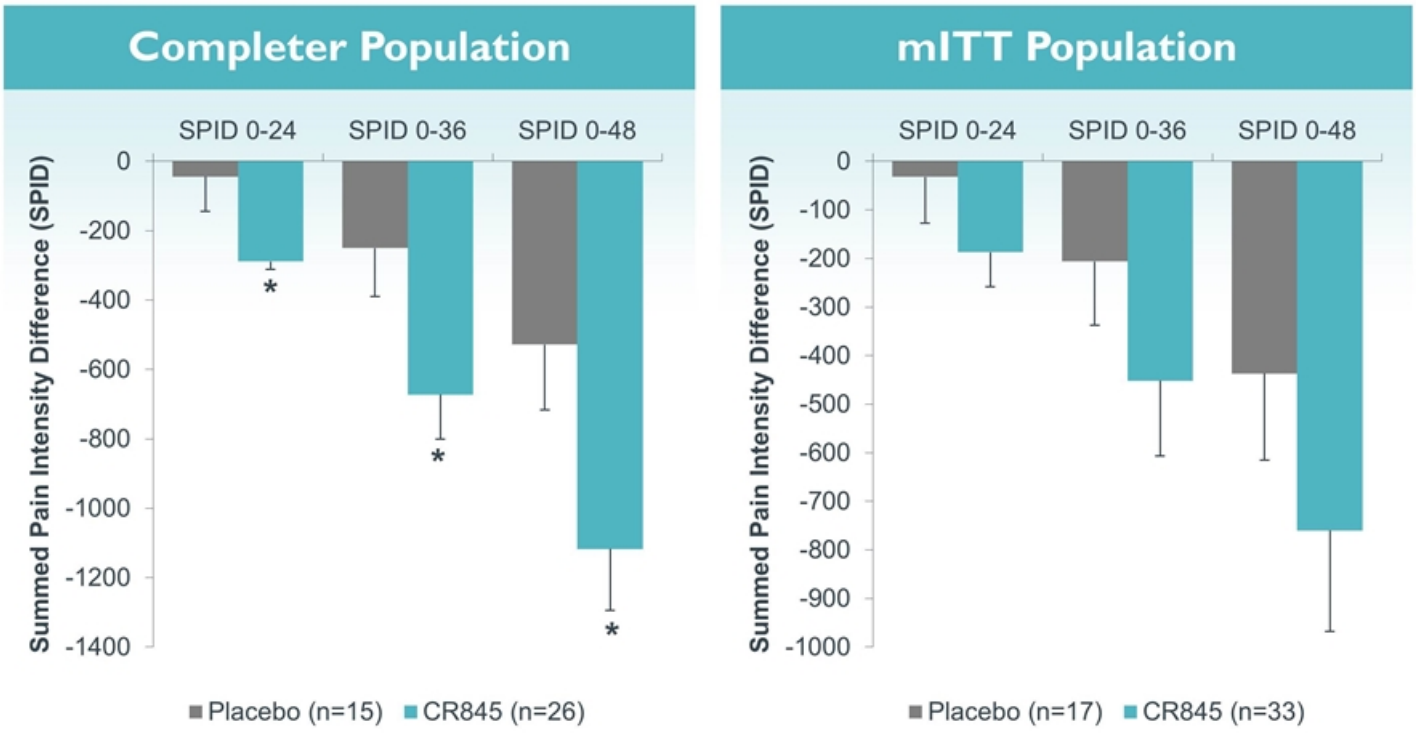
CR845 Phase 2 Bunionectomy Trial: Reduced Post-Operative Bunionectomy Pain

CLIN2003 Trial



*p,0.05,One-sided ANOVA with Treatment Group as a Main Effect.

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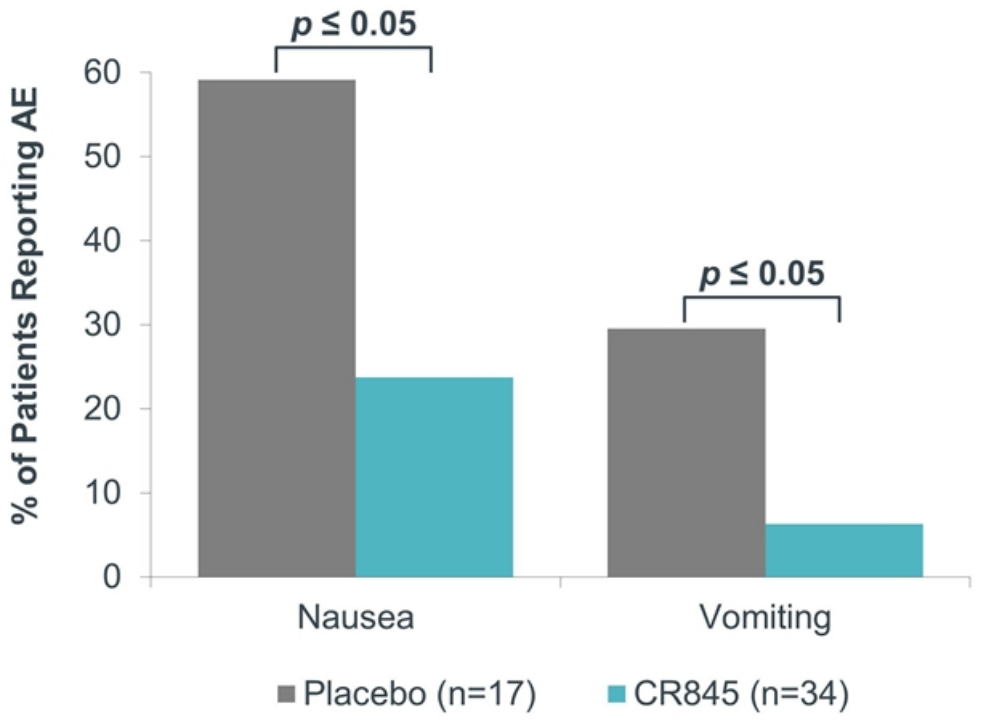
CR845 Phase 2 Bunionectomy Trial: Suppression Of Nausea And Vomiting

CLIN2003 Trial



Percentage of patients with nausea or vomiting was reduced 60% and 80%, respectively, with CR845. Differences are statistically significant (p<0.05, Fisher exact tests).

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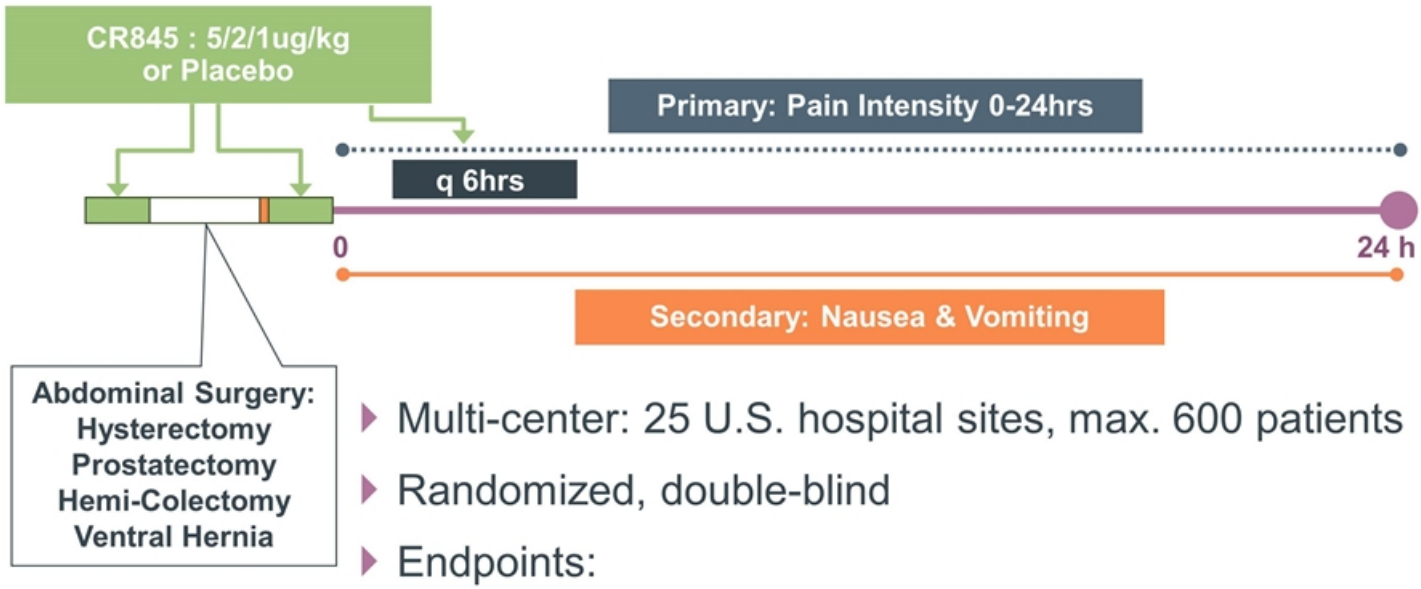
Ongoing CR845 Post-Op Pain Adaptive Phase 3 Abdominal Surgeries: Pre- and Post-Surgical Treatment

CLIN3001 Trial



- Multi-center: 25 U.S. hospital sites, max. 600 patients
- Randomized, double-blind
- Endpoints:
  - Pain intensity 0-24hrs
  - Nausea & Vomiting
  - Rescue medication used (IV morphine)
  - Global evaluation of medication

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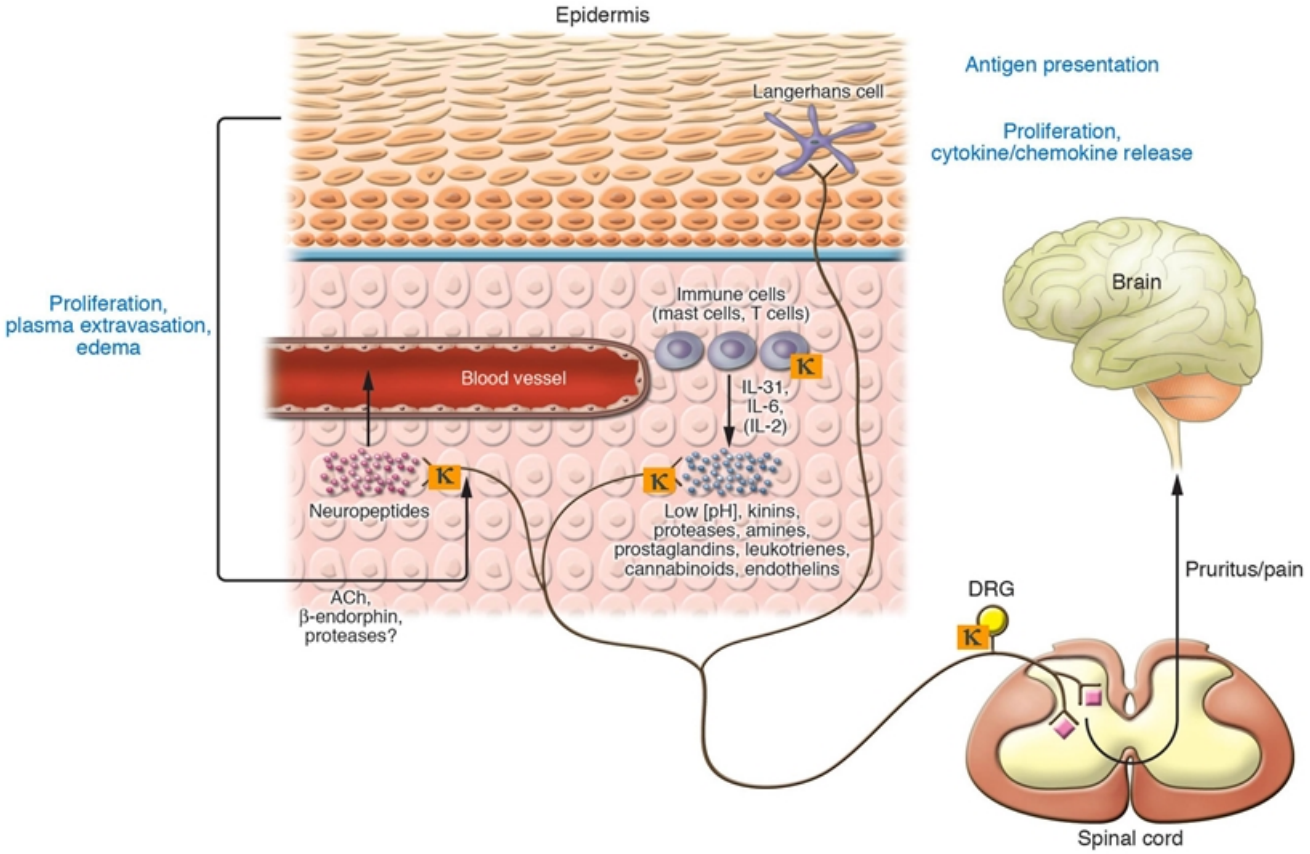
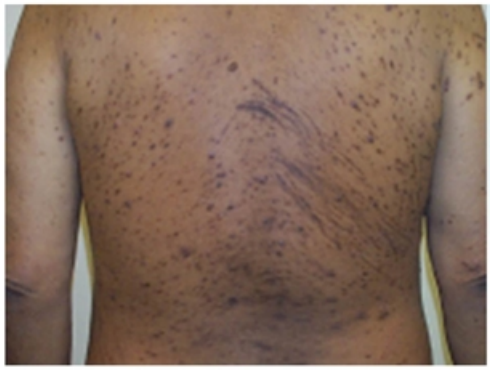
Pruritus And Pain – Common Pathway



Source: Paus et al.,J Clin Inv, 2006.

Uremic Pruritus (UP) in Dialysis Patients

- Chronic itching experienced by ESRD (End-Stage-Renal-Disease) patients requiring dialysis
- 30-42%[1-2] of dialysis patients experience moderate-severe UP
  - Reduces quality of life, increased negative health outcomes, mortality and cost
- Unresponsive to conventional itch medications: antihistamines, steroids



- *Most common on back, abdomen & arms*
- *Typically bilateral*
- *Excoriations in severe cases*

1.Ramakrishnan 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
2. 1. Pisoni RL, Wikstrom B, Elder SJ, et al. Pruritus in haemodialysis patients: international results from the Dialysis Outcomes and Practice Patterns Study (DOPPS). *Nephrol Dial Transplant.* 2006;21:3495-3505.

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Uremic Pruritus POC Phase 2 Trial Design

Primary Objectives

Part A

- To evaluate the PK profile of repeated doses of CR845 in hemodialysis patients over a one-week treatment period

Part B

- To evaluate the efficacy of CR845 compared to placebo in reducing the intensity of itch over a 2-week treatment period (1 dose selected based on Part A, 3 times/week post-dialysis) in hemodialysis patients with uremic pruritus

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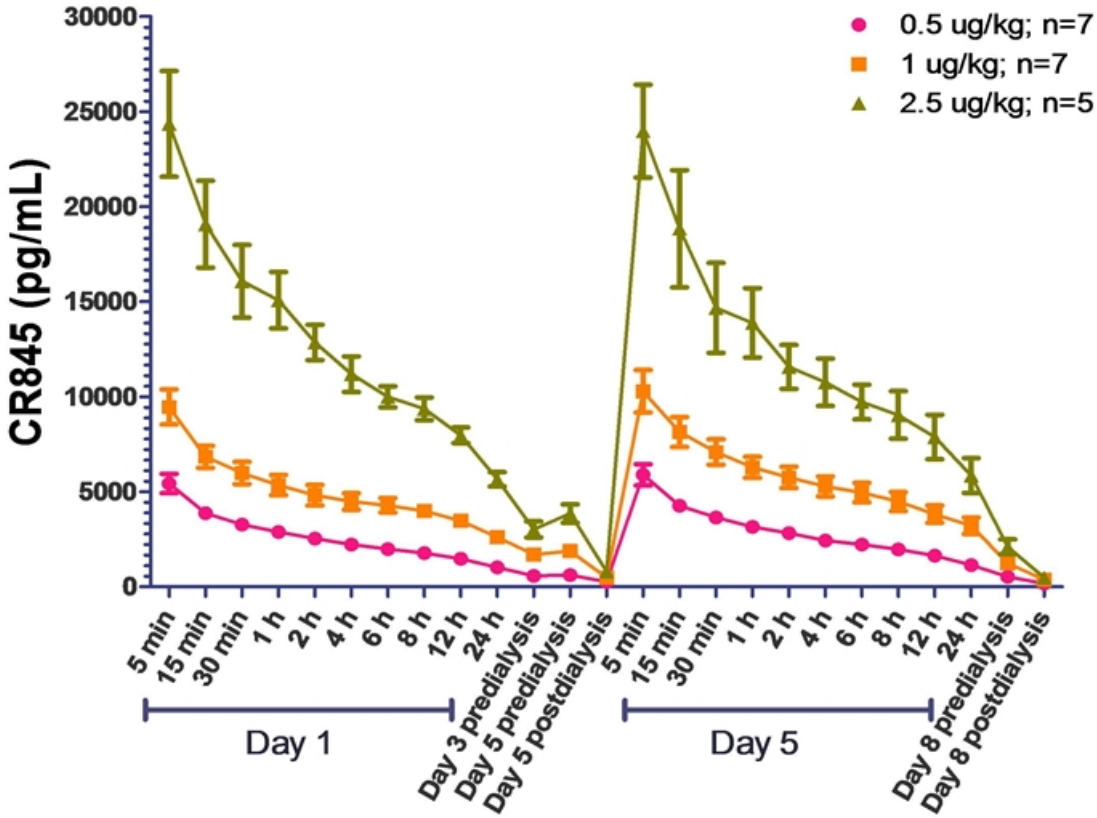
Part A Established Pharmacokinetics Allowing TIW Dosing

- CR845 Renally Excreted – Extended Half-Life: ~24 hours



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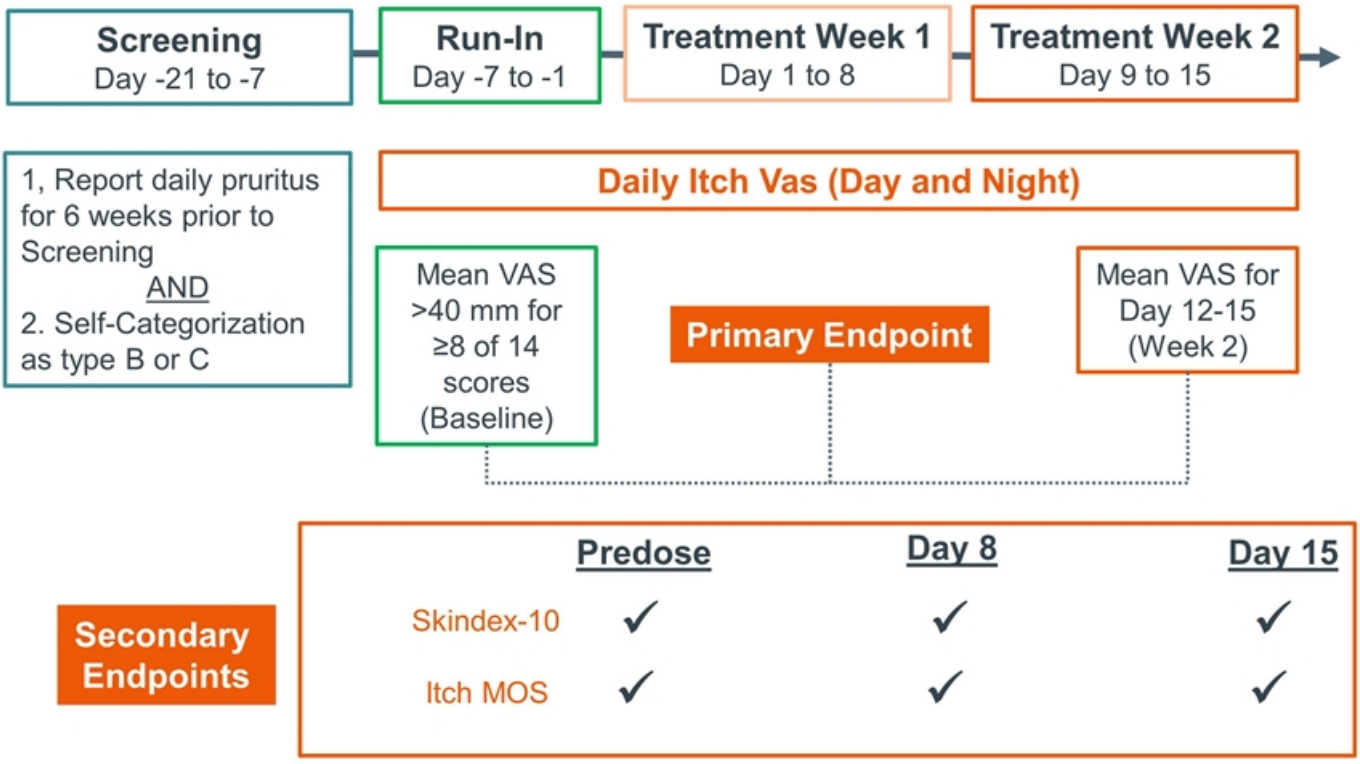
Uremic Pruritus POC Part B - Study Design



- 21 U.S. Sites: Randomized, double-blind, placebo-controlled

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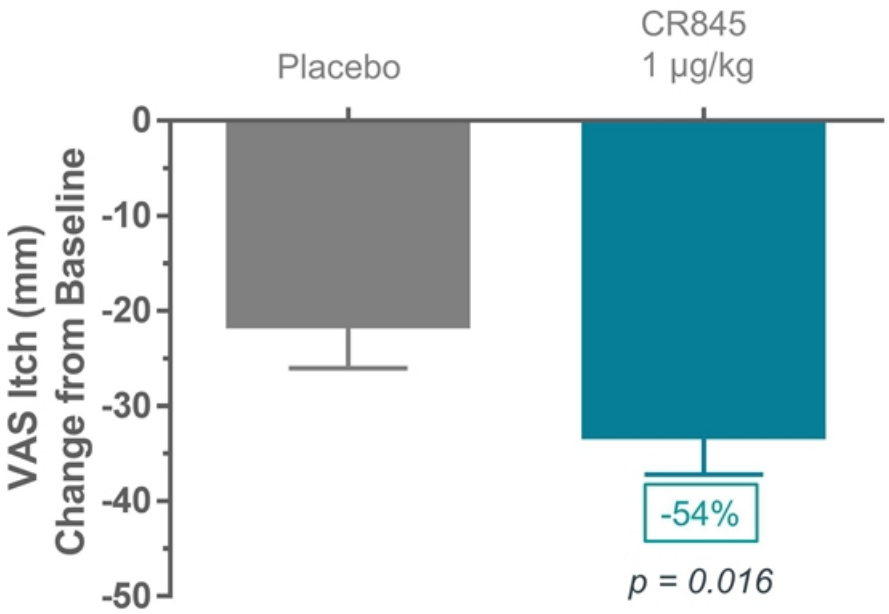
CR845 Significantly Reduced Itch Intensity



- Mean change from baseline (Run-in) to the average of Week 2 scores (Day 12 through 15)

Mean ± SEM MITT population.

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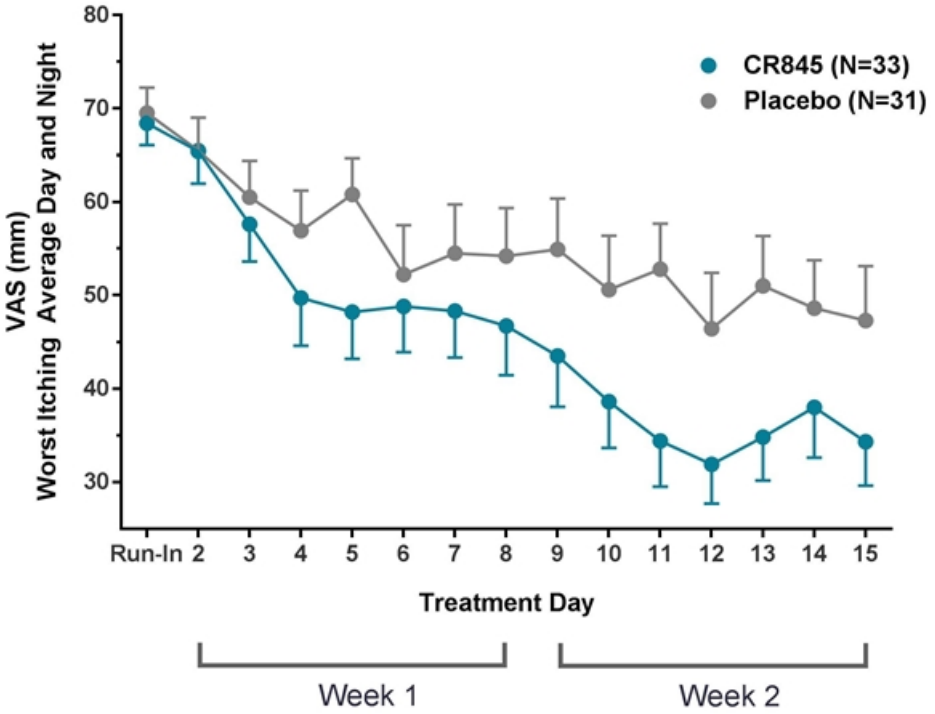
Itch Intensity Over 2 Weeks Of Treatment



- Reduction of itch intensity for patients treated with CR845 beginning on Week 1 that continues to improve through Week 2.
  - Patients on placebo show initial improvement that plateaus

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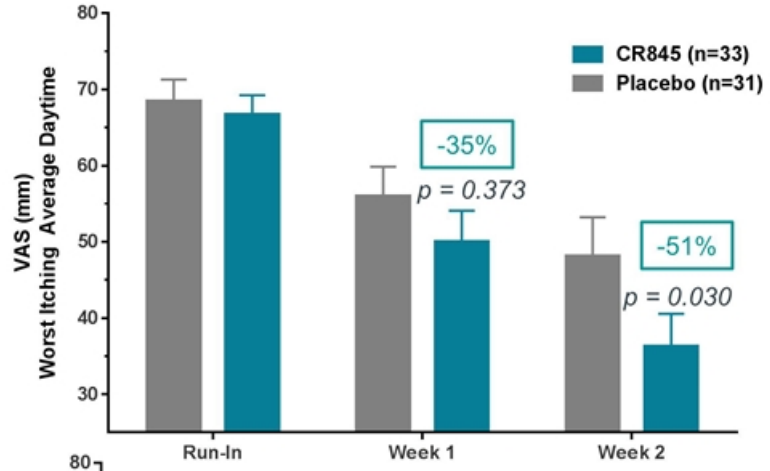
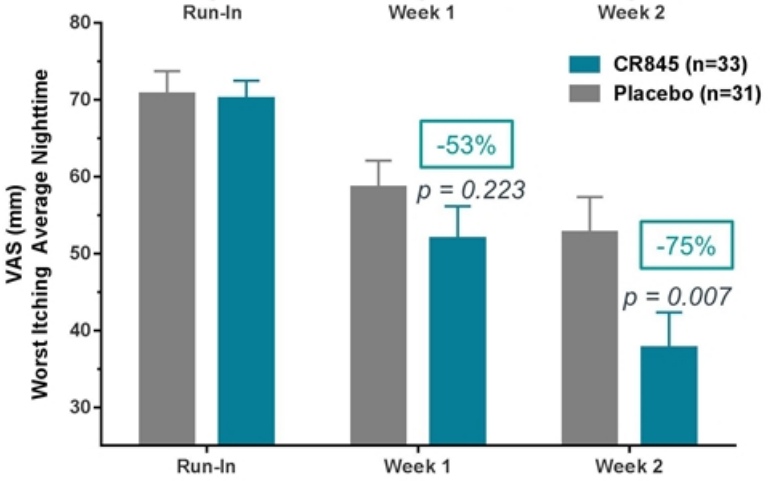
CR845: Significant Reduction In Worst Itch Intensity Reported For Both Day And Night Time By Week 2

Day



Night



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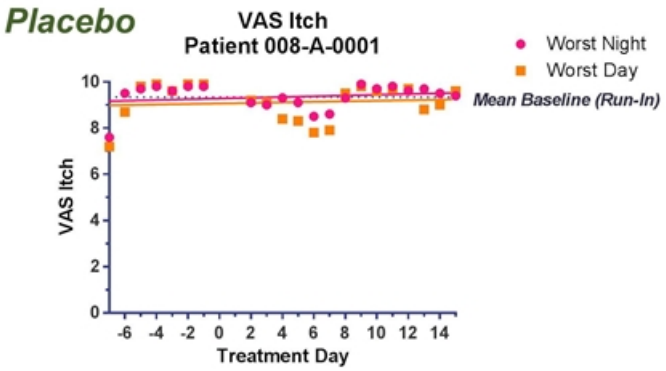
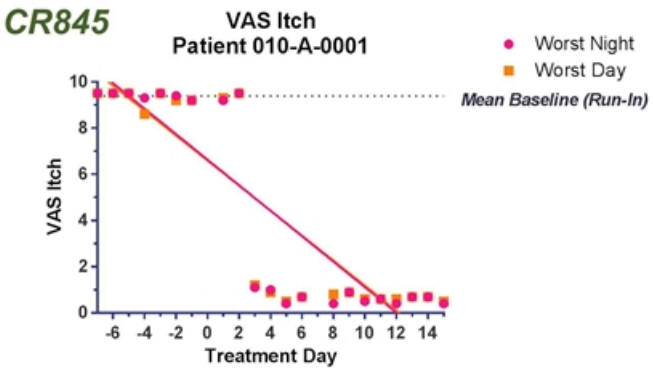
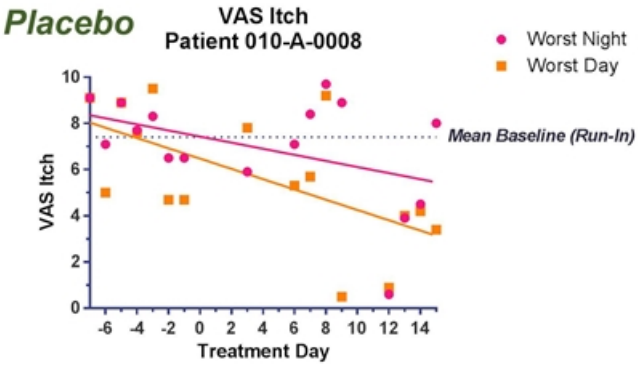
Example Individual Patient VAS profile

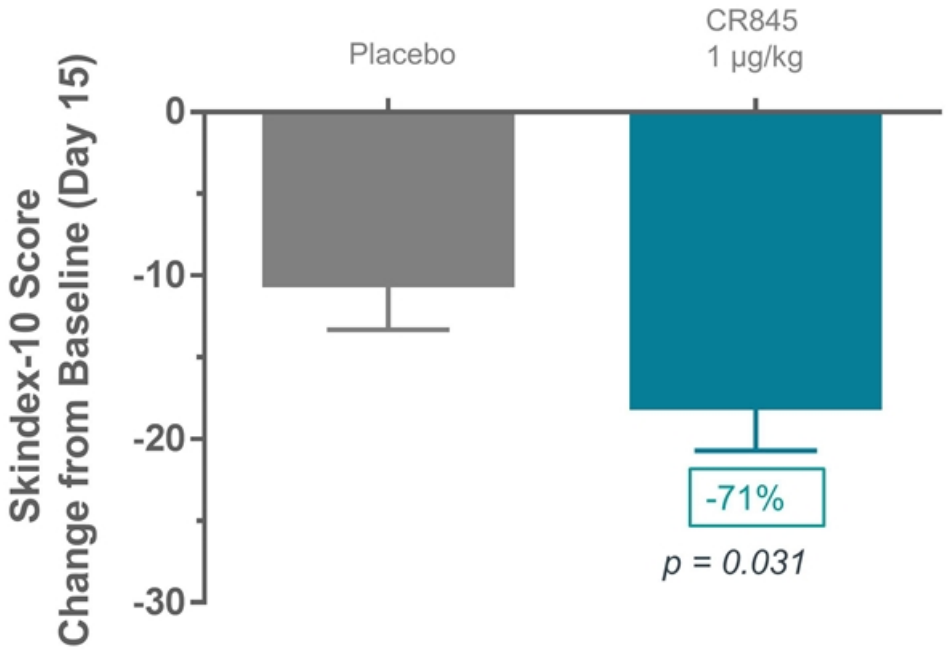






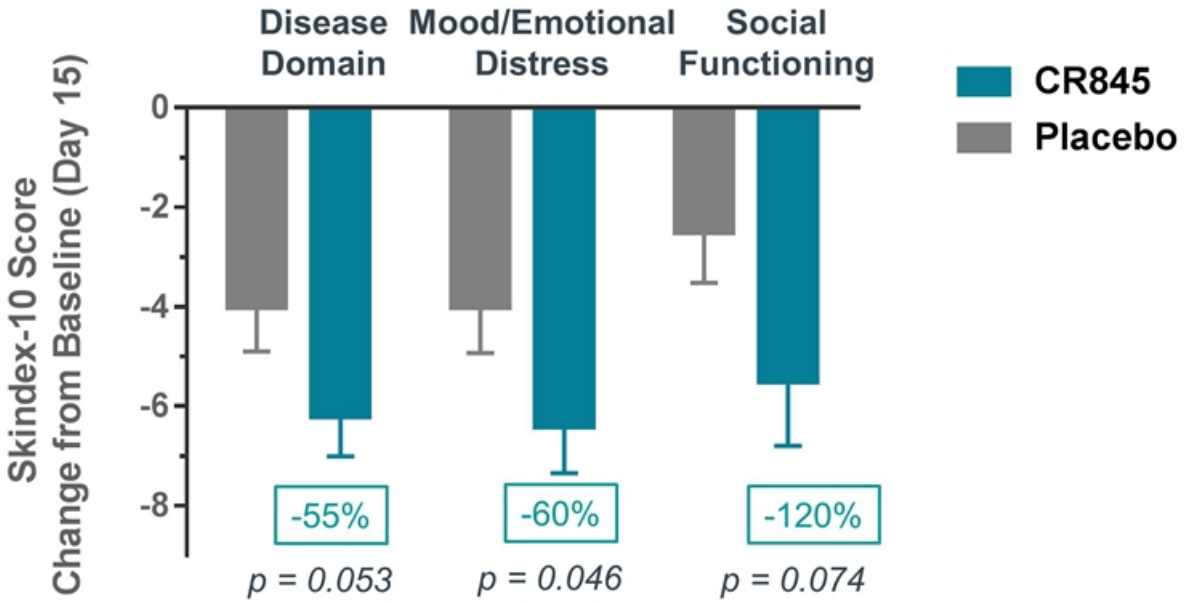
CR845 Improves Itch-Related Quality Of Life

- Skindex-10 is a validated scale that consists of 10 questions used to evaluate how the patient's itch affects their Quality of Life



Mean ± SEM MITT population.

CR845 Improves Itch-Related Quality Of Life Scores Across All Skindex 10 Domains



- After 2 weeks of treatment, patients reported trend for improvements across all aspects of their Quality of Life
- Trend in MOS Scale for patients treated with CR845 on overall improvement in their sleep: - 62% compared to placebo (non-statistical)

Mean ± SEM MITT.

CARA THERAPEUTICS

CR845 Was Well Tolerated

System Organ Class Preferred Term	Placebo (N=32) n (%)	CR845 (N=33) n (%)	Total (N=65) n (%)
Gastrointestinal disorders			
Diarrhoea	2 (6.3)	1 (3.0)	3 (4.6)
Nausea	2 (6.3)	2 (6.1)	4 (6.1)
Nervous System disorders			
Dizziness	0 (0)	2 (6.1)	2 (3.1)
Headache	2 (6.3)	2 (6.1)	4 (6.1)
Hypoaesthesia	0 (0)	3 (9.1)	3 (4.6)
Skin and Subcutaneous disorders			
Pruritus	1 (3.1)	2 (6.1)	3 (4.6)
Vascular disorders			
Hypotension	2 (6.3)	2 (6.1)	4 (6.1)

- No serious adverse events; most TEAEs were mild – moderate in severity
- No discontinuations due to AEs

CARA THERAPEUTICS

Upcoming Projected Clinical Milestones

2016

Interim Data Abdominal Pain Trial	1H, 2016
Initiation Uremic Pruritus Phase 2/3 Program	1H, 2016
Initiation Phase 2b Oral OA Trial	2H, 2016
Initiation 2nd Phase 3 Acute Pain Trial	2H, 2016

CARA THERAPEUTICS

Cara: Financial Highlights

As of September 30, 2015

- Cash and Cash Equivalents $111.1M
- Milestone revenue – 9 months YTD $2.3M
- Net loss – 9 months YTD $15.2M
- Shares outstanding 27,231,583
- IPO completed 2/5/2014 – $56M: Follow-On Offering 7/29/15 - $75M

CARA THERAPEUTICS

Cara: Developing First-in-Class Peripheral Opioid

- **Novel opioids without traditional opioid side effects**
  - Kappa opioid agonists with unique pharmacology and chemotype
  - NCEs with patent protection through at least 2027
  - MOA: Anti-Nociceptive/Anti-Inflammatory & Anti-Pruritic
- **Lead candidate, I.V. CR845 - Phase 3 Program post-op pain 9/15**
  - Positive results in three Phase 2 trials in over 250 patients
  - Statistically significant reductions in pain and opioid-related adverse events across all three trials
- **Successful Phase 2 Trial of I.V. CR845 in Uremic Pruritus**
  - Primary & Secondary Endpoints: Reduction in worst itch & improved QoL
  - Completed FDA meeting Q4, 2015
- **Completed Phase 2a Osteoarthritis Trial Q4, 2015**
- **IPO completed 2/5/2014 – $56M: Follow-On Offering 7/29/15 - $75M**

CARA THERAPEUTICS