**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) **August 12, 2021**

# 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**<br>**107 Elm Street, 9th Floor**<br>**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 | 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 August 12, 2021, Cara Therapeutics, Inc. (the "Company") made available an updated corporate presentation that the Company may utilize from time to time in connection with investor meetings, which can be found on the Company's website (the "Corporate Presentation"). The Corporate Presentation is furnished as Exhibit 99.1 and incorporated by reference in this Item 7.01.

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.** | **Description** |
|---|---|
| 99.1 | Corporate Presentation, dated August 12, 2021 |
| 104 | Cover page interactive data file (formatted as Inline XBRL) |

**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/ THOMAS REILLY**

Thomas Reilly
Chief Financial Officer
(Principal Financial and Accounting Officer)

Date: August 12, 2021

**Exhibit 99.1**

# Targeting Pruritus with First-In-Class Therapeutics

AUGUST 12TH, 2021

CARA™ THERAPEUTICS

# Forward Looking Statements

Statements contained in this presentation 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 expected timing of the enrollment and data readouts from the Company's ongoing clinical trials, the potential results of ongoing clinical trials, timing of future regulatory and development milestones for the Company's product candidates and potential commercialization of KORSUVA Injection for CKD-aP, the expected timeline for conducting meetings with the FDA concerning the Company's product candidates, the potential for the Company's product candidates to be alternatives in the therapeutic areas investigated, the Company's expected cash reach, and the potential impact of COVID-19 on the Company's clinical development and regulatory timelines and plans. 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 Therapeutics' filings with the Securities and Exchange Commission, including the "Risk Factors" section of the Company's most recent Annual Report on Form 10-K for the year ending December 31, 2020 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.

Cara Therapeutics undertakes no obligation to update such statements to reflect events that occur or circumstances that exist after the date on which they were made.



CARA THERAPEUTICS

# Creating life-changing pruritus therapeutics

**Cara Therapeutics is a close-knit group of scientists, medical experts, and industry leaders deeply committed to the science of changing lives. Our proprietary, novel therapies are poised to make a significant impact for the millions who have been overlooked.**

| Our Mission: | Our Vision: |
| --- | --- |
| Transform the way pruritus is treated to bring quality to the lives of those who suffer. | Inspire new ways of thinking about pruritus treatment to elevate the standard of care far beyond what has been considered possible. |

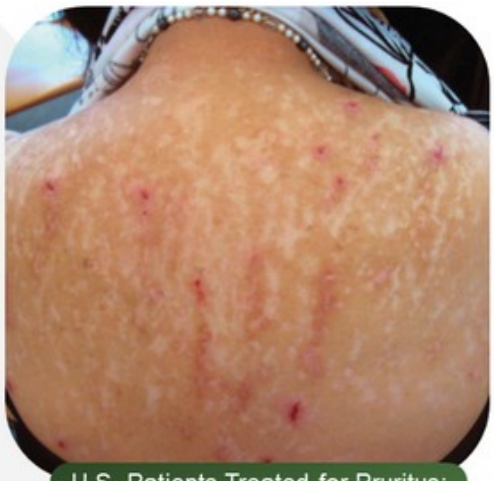
# The Far-Reaching Impact of Pruritus

**Chronic Kidney Disease (CKD)**
Pruritus occurs in both patients on hemodialysis and those with CKD not yet on dialysis — **~40-60%**

**Chronic Liver Disease (CLD)**
Patients with CLD, especially cholestatic liver disease experience significant pruritus — **~30-50%**

**Atopic Dermatitis (AD)**
Pruritus is a defining symptom of AD — **~100%**

**Notalgia Paresthetica (NP)**
Pruritus is the defining symptom of NP — **~100%**



U.S. Patients Treated for Pruritus:
**>20 Million**
SCRIPTS ANNUALLY[1]

 | Source: IQVIA Analysis, 2021.

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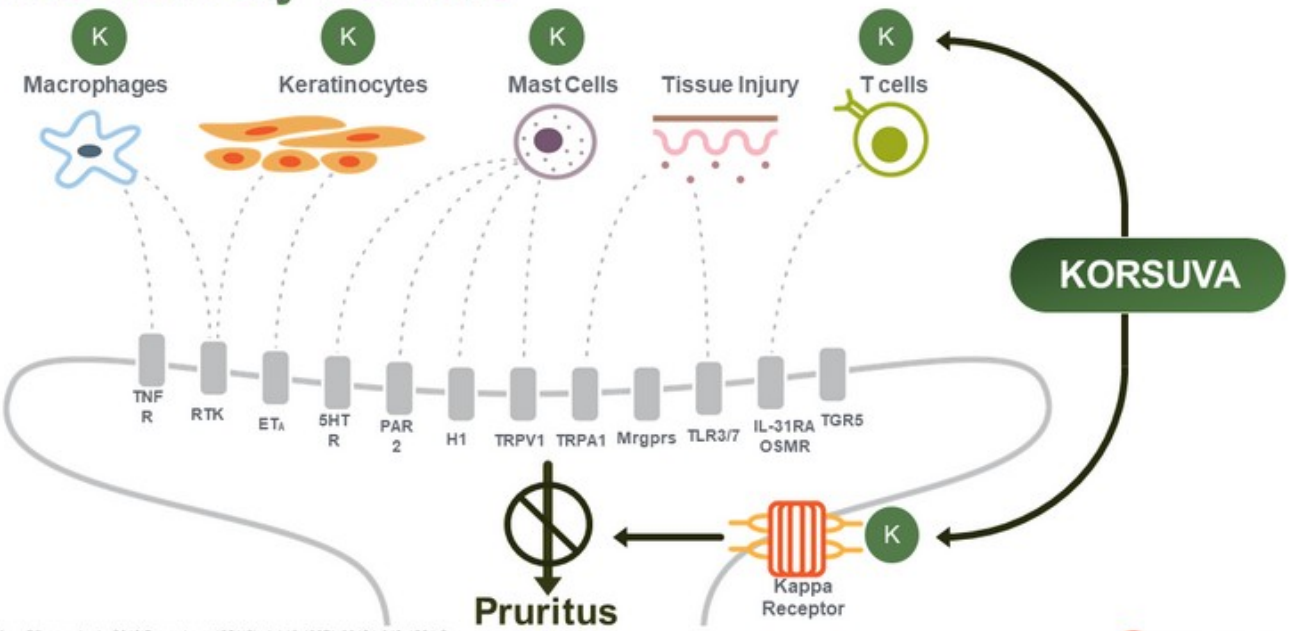
# KORSUVA[1] (Difelikefalin) Directly Blocks Pruritus Sensory Neurons




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

Reference: 1. The FDA has conditionally accepted KORSUVA™ as the trade name for difelikefalin injection.

Difelikefalin injection is an investigational drug product and its safety and efficacy have not been fully evaluated by any regulatory authority.



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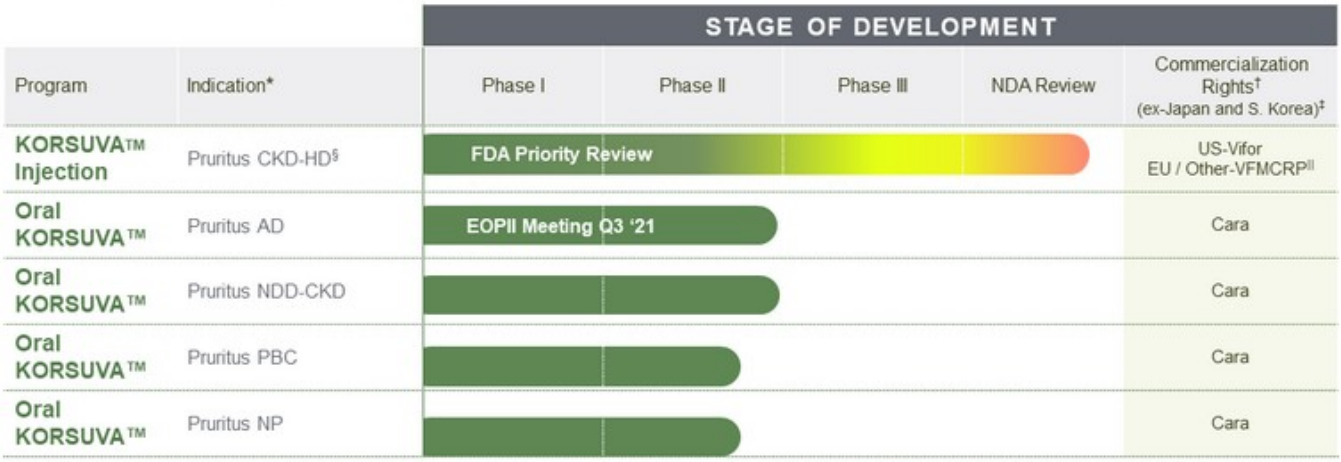
# Cara Therapeutics Pipeline




*Cara Therapeutics has investigated KORSUVA™ for post-operative pain.
†Vifor has commercial rights in Non-US Fresenius Medical Care dialysis clinics under a profit-share arrangement.
‡Commercialization rights to KORSUVA™ in defined indications—Japan: Maruishi Pharma; South Korea: CKD Pharma.
§PDUFA date is August 23, 2021.
||VFMCRP and Cara have rights to promote in Fresenius clinics in the US under a profit-share agreement.
CKD-HD: Chronic Kidney Disease-Hemodialysis; NDD—CKD: Non-Dialysis Dependent-Chronic Kidney Disease; AD: Atopic Dermatitis; PBC: Primary Biliary Cholangitis; NP: Notalgia Paresthetica.

The FDA has conditionally accepted KORSUVA™ as the trade name for difelikefalin injection.
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# KORSUVA[1] (Difelikefalin) Injection for Dialysis Patients

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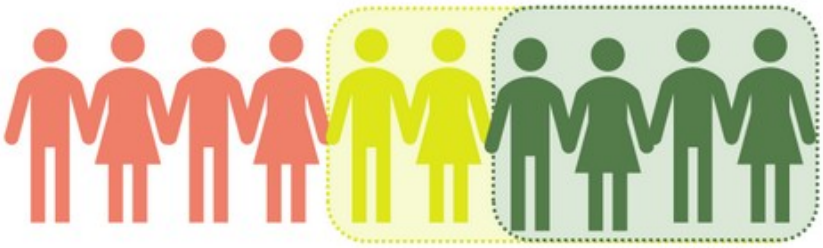
**Reference: 1**. The FDA has conditionally accepted KORSUVA™ as the trade name for difelikefalin injection. Difelikefalin injection is an investigational drug product and its safety and efficacy have not been fully evaluated by any regulatory authority.

# KORSUVA[1] (Difelikefalin) Injection For CKD-associated Pruritus (CKD-aP) in Dialysis Patients



**>500K[2]**

**patients on dialysis**

**60%**

**of ESRD patients have pruritus[3,4]**

**~40%**

**have moderate to severe pruritus**

**Serious intractable systemic pruritus**

CKD-aP associated with worsening 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

**NDA Priority Review**

NDA filing – **PDUFA Aug 23 '21**[5]

U.S. launch - **2H, 2021**[5]



**Reference: 1.** The FDA has conditionally accepted KORSUVA™ as the trade name for difelikefalin injection. Difelikefalin injection is an investigational drug product and its safety and efficacy have not been fully evaluated by any regulatory authority. **2.** National Kidney Foundation. . *3. Pisoni RL, Wikstrom B, Elder SJ, et al. Nephrol Dial Transplant. 2006;21:3495–3505. 4. Ramakrishnan et al. International Journal of Nephrology and Renovascular Disease. 2014:7 1–12* **5.** NDA accepted by FDA with priority review PDUFA date Q3 2021. Launch dependent on FDA approval

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# KORSUVA[1] (Difelikefalin) Injection NDA Review Status

- Mid-Cycle Review Complete April 2021
  - No significant issues identified to date
- Late Cycle Review Complete June 2021
  - No substantive issues identified to date
  - An Advisory Committee Meeting is not planned
  - No issues related to risk management identified
  - Scheduling (or not) under review

**PDUFA Target Action Date August 23rd, 2021**



References: 1. The FDA has conditionally accepted KORSUVA™ as the trade name for difelikefalin injection.
Difelikefalin injection is an investigational drug product and its safety and efficacy have not been fully evaluated by any regulatory authority.

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# IV KORSUVA[1] (Difelikefalin) Projected Milestones–2021 & 2022


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 Assumes approval without DEA review & no CMS review lag

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# KORSUVA[1] (Difelikefalin) Injection: U.S. Commercial Strategy Cara/Vifor Commercial License

Summary Terms (Ex-Fresenius Medical Care Clinics)

- $150M Up-Front ($100M Cash/$50M Equity) received in Q3 2020
- $50M Regulatory approval ($50M Equity)
- US Market Profit split (Ex-FMC Clinics): Cara 60% : Vifor 40%
- $240M US Commercial Milestones

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VIFOR PHARMA



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# KORSUVA[1] (Difelikefalin) Injection: U.S. Commercial Strategy Cara/Vifor Commercial License

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VIFOR PHARMA

Employ Vifor established Nephrology commercial organization

- 100+ sales FTEs: Mircera, Velphoro, Venofer, Veltassa
- Existing relationships with US LDOs, MDOs and IDOs
- Established market access team
- Existing supply chain organization
- Track record of successful dialysis launches (e.g., Micera)

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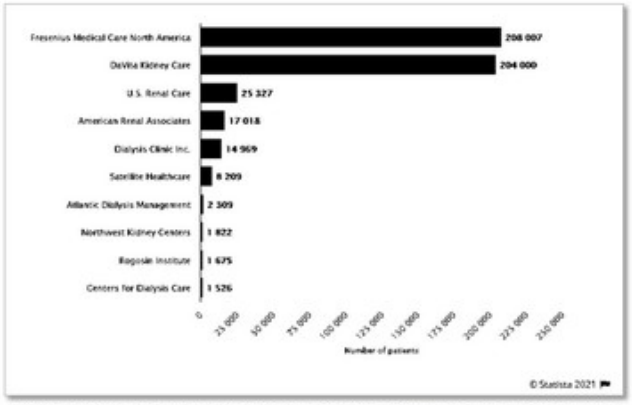
# Highly Consolidated Market Can Lead to Rapid Uptake

**NUMBER OF HEMODIALYSIS PATIENTS BY DIALYSIS ORGANIZATION – 2019** [1]




~80% of Dialysis Patients in 2 Customers; ~90% of Dialysis Patients in 6 Customers

**PARSABIV - MOST RECENT LAUNCH INTO HD SPACE HAD RAPID UPTAKE** [2]


Source
(1) Leading dialysis providers by number of patients U.S. 2019 | Statista
(2) AMGEN Annual Report on Form 10-K for the fiscal year ended Dec 31, 2020, filed with the SEC on Feb 9, 2021



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# Established Ex-US Commercial Agreements: KORSUVA Injection

| | |
|---|---|
| VIFOR FRESENIUS MEDICAL CARE RENAL PHARMA | Tiered Royalty By Sales: **EU**<br>$440 million Commercial Milestones |
| Maruishi Pharmaceutical Co., Ltd. | Tiered Royalty By Sales: **Japan**<br>~$10 million Commercial Milestone# |
| ChongKunDang | Tiered Royalty By Sales: **S. Korea** |

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 # 1 Billion Yen

# Oral KORSUVA[1] (Difelikefalin): Potential Broad Anti-Pruritic

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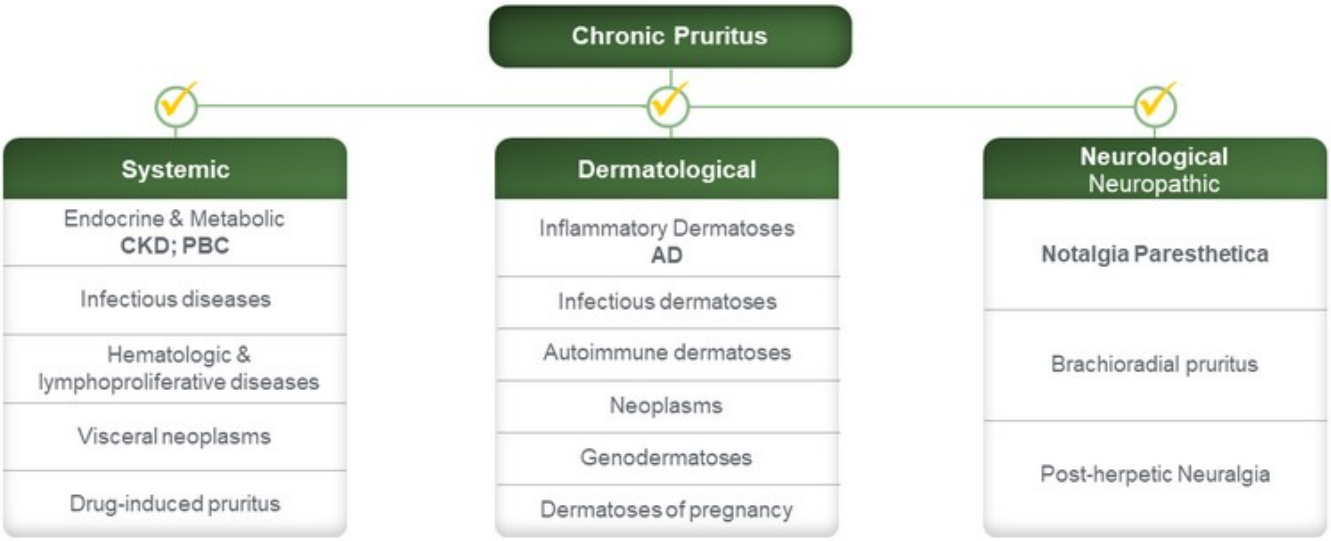
# Key Chronic Pruritus Categories




 Adapted from: Weisshaar et al. European S2k Guideline on Chronic Pruritus. Acta Derm Ven April 2019; 99(5): 469-506; Stander et al Clinical Classification of Itch Acta Derm Ven 2007; 87:291-294.

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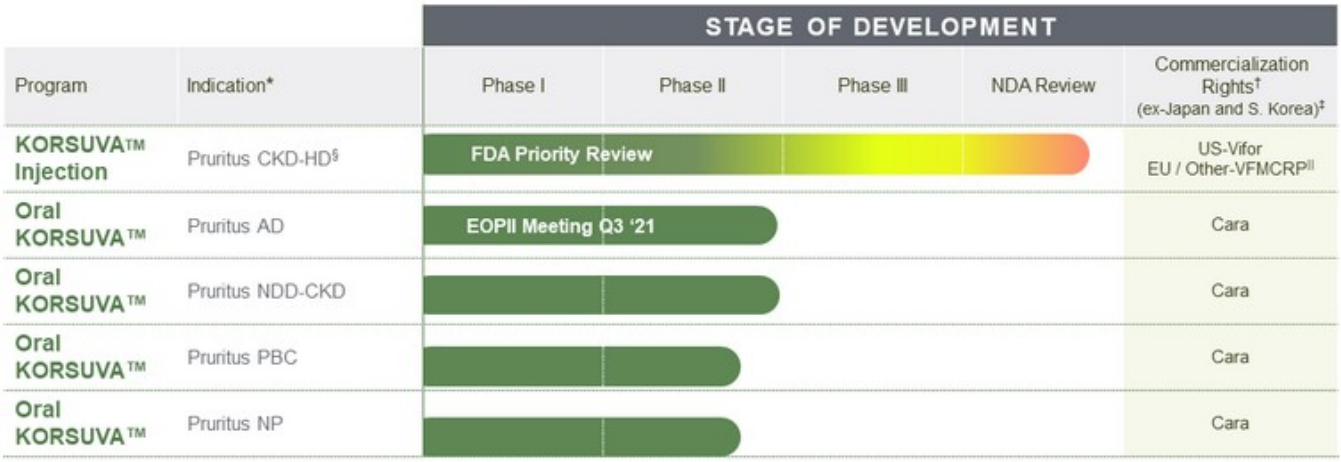
# Cara Therapeutics Pipeline

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# Oral KORSUVA[1] (Difelikefalin) for Mild-Moderate AD

**Moderate-Severe Pruritus**

**30 million**
US patients

**~80%**
Mild-Moderate Disease*

**~20%**
Severe Disease*

**Approved Therapies**

Topical Steroids & Immunomodulators

Injectable Biologic

*Silverberg JI. Public Health Burden and Epidemiology of Atopic Dermatitis. Dermatol Clin. 2017;35(3):283-289. Chiesa Fuxench ZC, Block JK, Boguniewicz M, et al. Atopic Dermatitis in America Study: A Cross-Sectional Study Examining the Prevalence and Disease Burden of Atopic Dermatitis in the US Adult Population. J Invest Dermatol. 2019;139(3):583-590. Barbarot S et al. Epidemiology of atopic dermatitis in adults: Results from an international survey. Allergy 2018; 1284-1293. Chovatiya R et al. Clinical phenotyping of atopic dermatitis using combined itch and lesional severity: A prospective observational study. Annals of Allergy, Asthma Immunology 2021.

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# Unmet Need in Mild-Moderate AD with Moderate-Severe Pruritus

- Pruritus is the most burdensome symptom of AD, however therapeutic development has focused on targeting pro-inflammatory mediators rather than pruritogenic pathways.
- Pruritus severity was found to be only weakly to moderately correlated with lesional severity [1]
- Only topical therapies are indicated for mild-moderate AD; with topical corticosteroids most commonly used.[2, 3, 4]
- Current topical therapies do not fully address chronic pruritus in mild-moderate AD, particularly if pruritus extends beyond the skin lesions.
  - High use of oral antihistamines; i.e. 16-44% of outpatient AD visits, but AD pruritus is not histaminergic [5, 6]
- Topical corticosteroid therapy have additional limitations, including HPA axis suppression, withdrawal effects, cutaneous side effects (skin atrophy, striae, telangiectasia) and poor adherence [7]

 **References:** 1. Chovatiya R et al. 2021; **2.** Eichenfield 2014; **3.** Eichenfield 2017; **4.** Mayba 2017; **5.** Mollanazar 2016; **6.** He 2018; 7. Hengge 2016

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# KARE: Phase 2 Study Design


**Primary Endpoint**

- Change from baseline in the weekly mean of the daily 24-hr Itch-Numeric Rating Scale (I-NRS) at Week 12

**Key Secondary Endpoint**

- Proportion of subjects achieving ≥4-point improvement in I-NRS at Week 12

**Other Secondary/Exploratory Endpoints**

- Sleep NRS
- DLQI
- PGIC
- Skin Assessments



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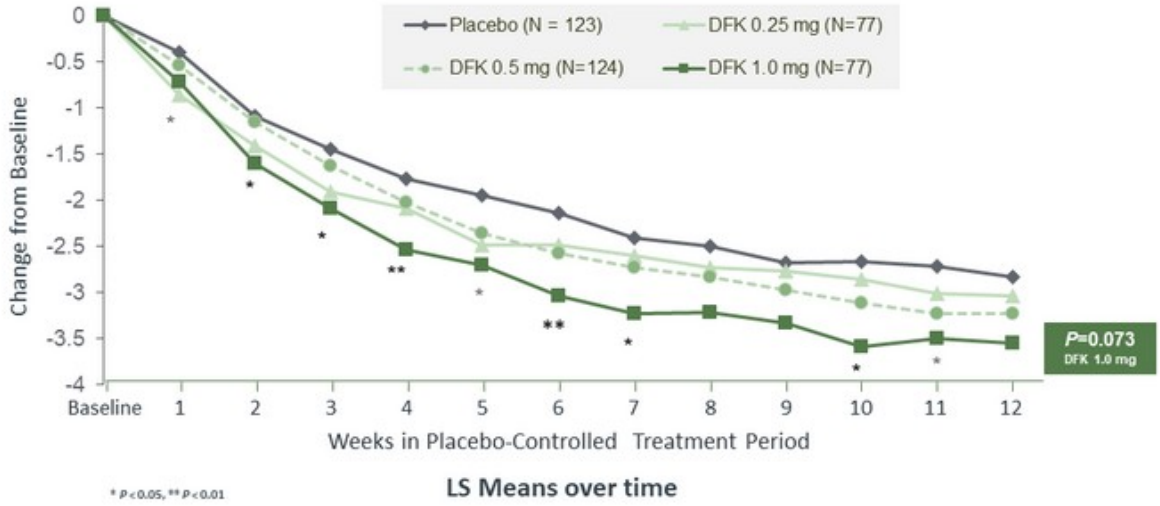
# Primary Endpoint: Change from Baseline in Daily I-NRS at Week 12 (ITT)

Significant improvement observed in 1.0 mg DFK vs placebo in majority of timepoints, starting at week 1




LS Means over time

21 | LS Means from MMRM with terms for treatment, week, week by treatment interaction, baseline score, and AD severity.
Missing data imputed using multiple imputation (MI) under missing at random (MAR) assumption. I-NRS scores after use of rescue are set to missing and then imputed with MI

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# KARE Trial Patient Population


**~64%**

Mild-Moderate Disease
BSA < 10%
(N=257)

**~36%**

Moderate-Severe Disease
BSA ≥ 10%
(N=144)



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# DFK 0.5 mg BID: Proposed Phase 3 Dose based on Benefit/Risk Profile in Mild-Moderate AD

**EFFICACY**

- Significant Improvement in pruritus:
  - 4-point responder analysis ($1^{o}$ endpoint in Phase 3)
- Improvements in QoL :
  - Sleep - 3-point responder analysis
  - DLQI - 4-point responder analysis
- Improvement in PGIC
- Low use of rescue medication (None in BSA<10)

**SAFETY**

- Well tolerated
  - Low incidence of GI TEAEs
  - AEs leading to discontinuation comparable to placebo



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# KARE: Baseline Disease Characteristics (BSA<10)

| | Placebo (N=79) | DFK 0.50 mg (N=82) |
|---|---|---|
| Duration of AD (yrs) – Mean (SD) | 21.5 (17) | 21.2 (16) |
| Baseline BSA (%) – Mean (SD) | 4.3 (2.5) | 4.55 (2.8) |
| Baseline EASI – Mean (SD) | 3.7 (2.6) | 3.98 (2.8) |
| Baseline IGA – n (%) | | |
| 2 | 48 (61) | 47 (57) |
| 3 | 31 (39) | 34 (42) |
| 4 | 0 | 1 (1.2) |
| Baseline I-NRS – Mean (SD) | 7.6 (1.3) | 7.7 (1.2) |
| Baseline DLQI – Mean (SD) | 12 (6.8) | 10.6 (5.9) |
| | | |
| Use of Rescue Medication | 1 (1.3%) | 0 |



BSA=Body Surface Area & <10% is mild/moderate AD; EASI scores ranges from 0 to 72;
IGA scores range from 0 to 4; I-NRS: Worst Itching Numeric Rating Scale (0 to 10) where 0 = no itch and 10 = worst itching imaginable.

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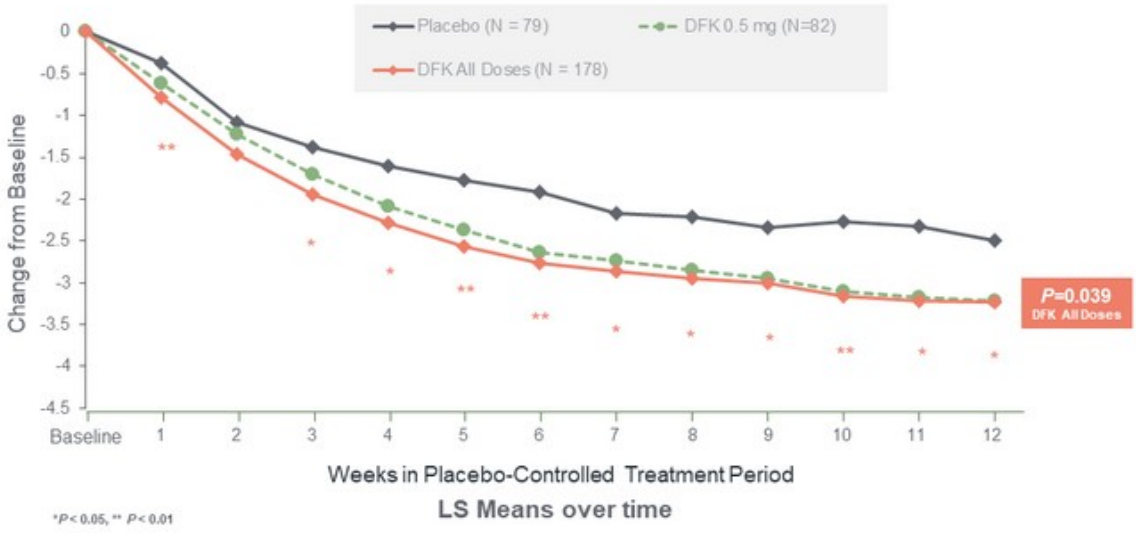
# Mild-Moderate AD (BSA <10)
# Change from Baseline in Daily I-NRS through Week 12




LS Means from MMRM with terms for treatment, week, week by treatment interaction, baseline score, and AD severity.
Missing data imputed using multiple imputation (MI) under missing at random (MAR) assumption. I-NRS scores after use of rescue are set to missing and then imputed with MI



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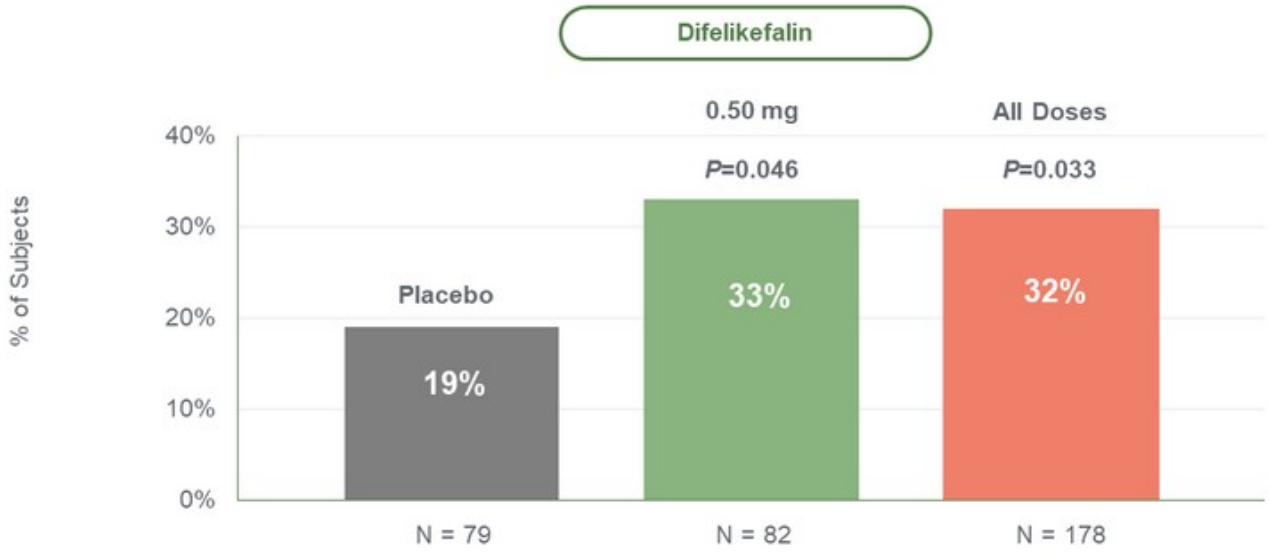
# Mild to Moderate AD (BSA <10)
# 4-point Responder Analysis through Week 12






Estimated percentage & P-value based on a logistic regression model with terms for treatment group and baseline I-NRS score. Patients who d/c early, or took rescue medication, or have missing data at Week 12, are considered as "non-responders"

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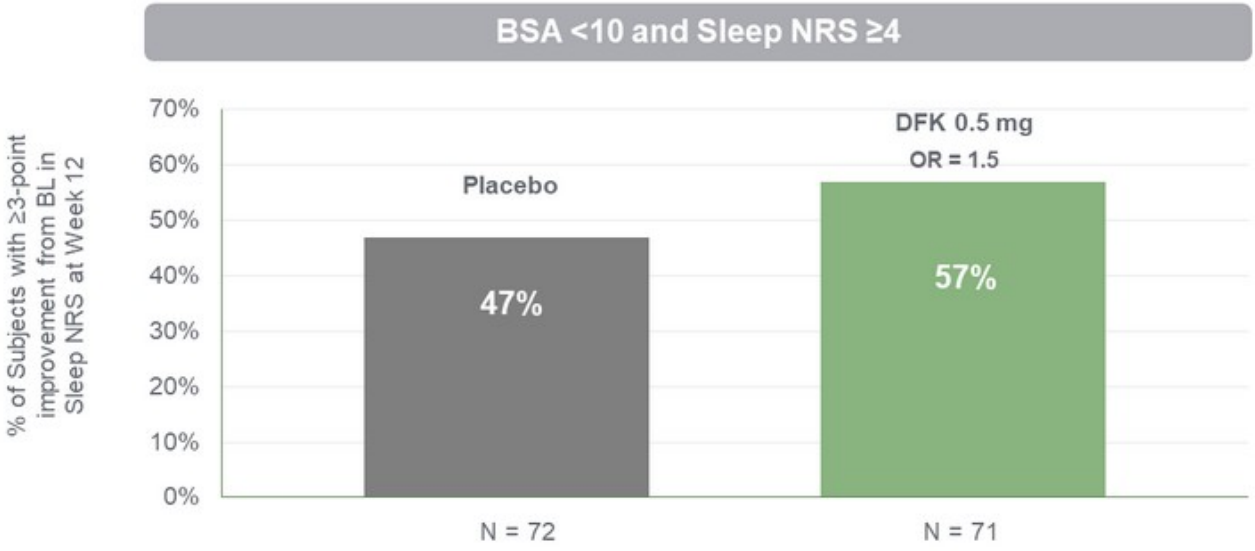
# Mild-Moderate AD (BSA <10)
# 3-point Improvement in Sleep NRS through Week 12






Estimated percentage & P-value based on a logistic regression model with terms for treatment group and baseline I-NRS score.
Patients who d/c early, or took rescue medication, or have missing data at Week 12, are considered as "non-responders"

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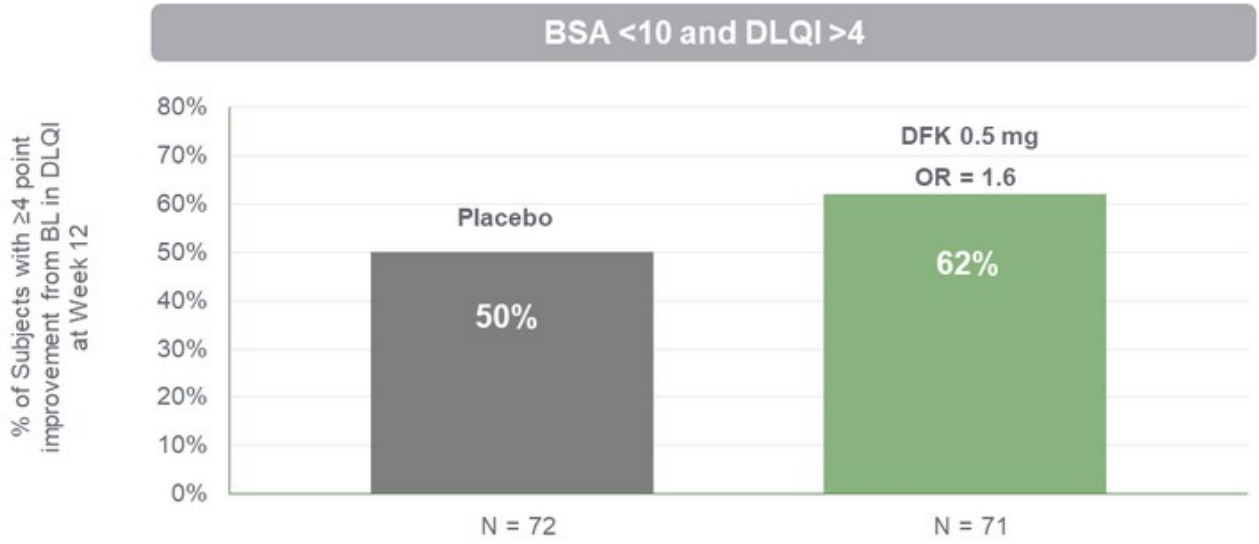
# Mild-Moderate AD (BSA <10)
# Subjects with ≥ 4-point Improvement in DLQI at Week 12




 Chi-square Test; Patients who d/c early, used rescue meds, or have missing data in Week 12 are included as "non-responders"

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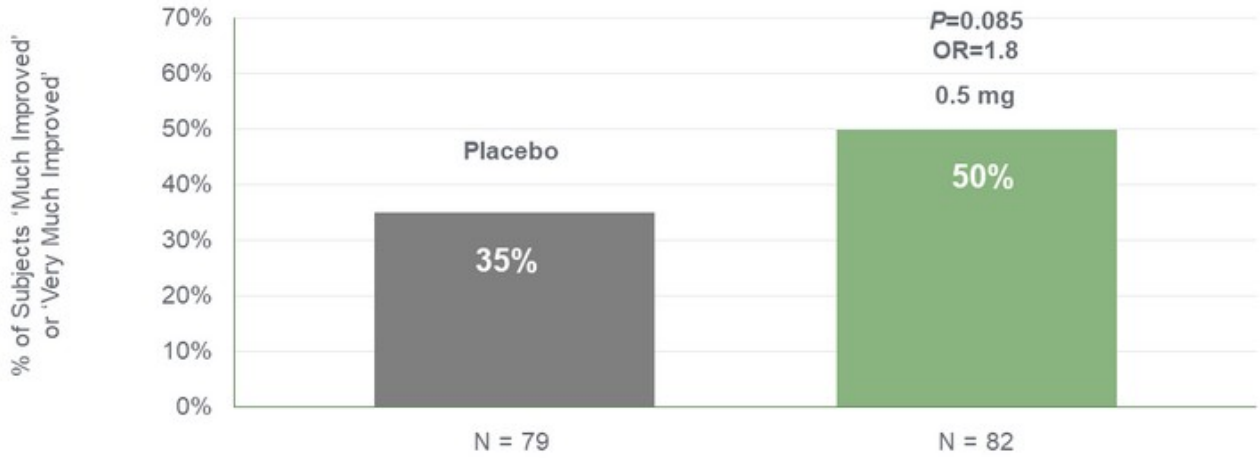
# Mild-Moderate AD (BSA <10)
# Patient Global Impression of Change at Week 12




 | Chi-square test; Observed values

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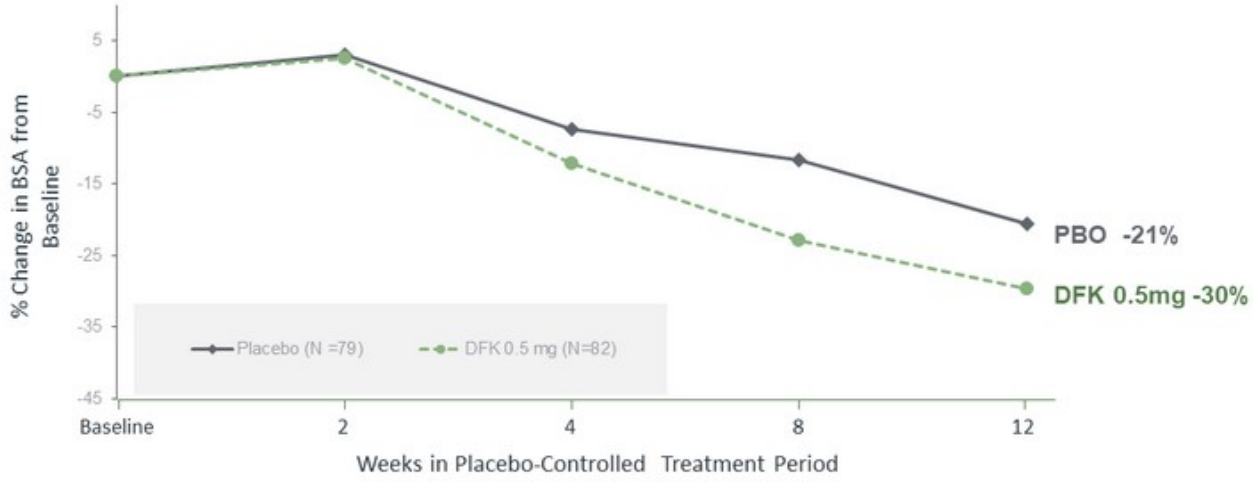
# Mild-Moderate AD (BSA < 10)
# % Change in EASI from baseline over time



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# Summary of Adverse Events

| | Placebo (N=123) | DFK 0.50 mg (N=124) |
|---|---|---|
| Subjects with at least one TEAE, n (%) | 54 (43.9%) | 49 (39.5%) |
| Subjects with at least one serious TEAE, n (%) | 0 | 1 (0.8%) |
| Subjects with TEAE resulting in treatment discontinuation, n (%) | 4 (3.3%) | 1 (0.8%) |



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# Most Commonly Reported TEAEs (Safety Population)

| Treatment-emergent Adverse Events at ≥5% frequency; n (%) | Placebo (N=123) | DFK 0.50 mg (N=124) |
|---|---|---|
| Abdominal pain* | 13 (10.6%) | 11 (8.9%) |
| Nausea | 11 (8.9%) | 6 (4.8%) |
| Dry Mouth | 0 | 2 (1.6%) |
| Headache | 5 (4.1%) | 3 (2.4%) |
| Dizziness | 2 (1.6%) | 3 (2.4%) |
| Hypertension ** | 1 (0.8%) | 3 (2.4%) |

Safety analyses performed in the safety population, defined as all randomized patients who received ≥1 dose of study drug based on actual treatment received.
*Includes PTs abdominal pain, abdominal pain upper, abdominal discomfort
**Includes preferred terms of hypertension and blood pressure increased



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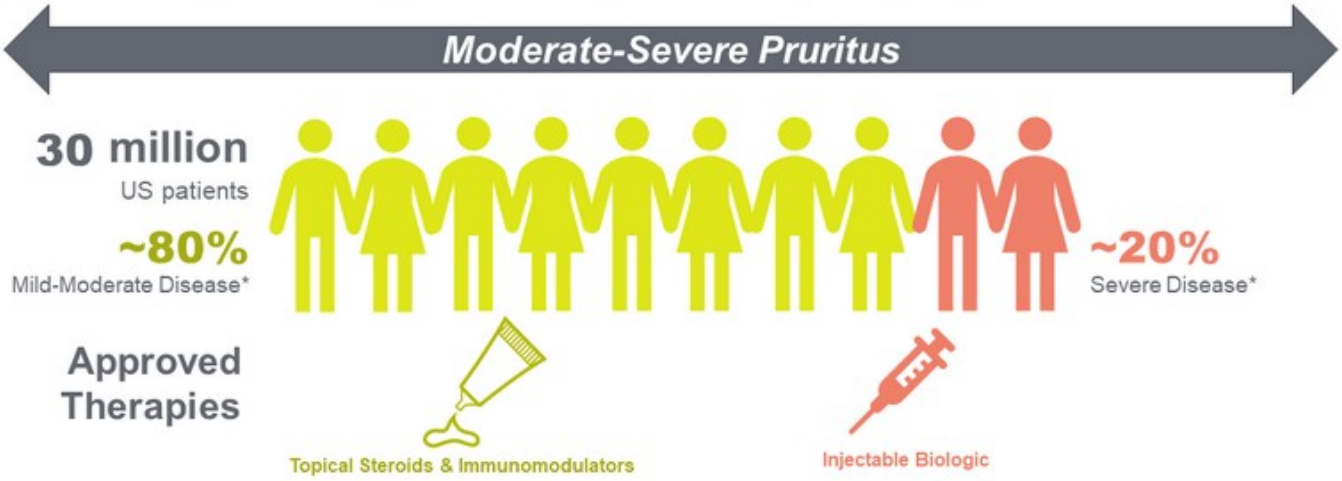
# Oral KORSUVA[1] (Difelikefalin) for Mild-Moderate AD

- High unmet need for systemic anti-pruritic therapy in Mild-Moderate AD
- KARE data support that breaking the itch-scratch cycle with DFK may manage subjects with mild-to-moderate AD




*Silverberg JI. Public Health Burden and Epidemiology of Atopic Dermatitis. Dermatol Clin. 2017;35(3):283-289. Chiesa Fuxench ZC, Block JK, Boguniewicz M, et al. Atopic Dermatitis in America Study: A Cross-Sectional Study Examining the Prevalence and Disease Burden of Atopic Dermatitis in the US Adult Population. J Invest Dermatol. 2019;139(3):583-590. Barbarot S et al. Epidemiology of atopic dermatitis in adults: Results from an international survey. Allergy 2018; 1284-1293. Chovatiya R et al. Clinical phenotyping of atopic dermatitis using combined itch and lesional severity: A prospective observational study. Annals of Allergy, Asthma Immunology 2021.

**References: 1**. The FDA has conditionally accepted KORSUVA™ as the trade name for difelikefalin injection.

Difelikefalin injection is an investigational drug product and its safety and efficacy have not been fully evaluated by any regulatory authority.



CARA THERAPEUTICS

# Oral KORSUVA[1] (Difelikefalin) in Mild-Moderate AD: Next Steps

- Oral KORSUVA™ 0.5mg bd proposed dose for Phase 3 Program demonstrated:
  - A statistically significant antipruritic effect in mild-to-moderate AD and moderate-to-severe pruritus.
  - Numerical improvement in quality of life and sleep
  - Well-tolerated

- EOP2 Meeting scheduled for Q3 2021

- Abstract to be submitted to scientific congress

**Subject to discussions with FDA, aim to initiate Phase 3 trial Registration Program In Mild-to-Moderate Atopic Dermatitis Patients by end of 2021**



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CARA THERAPEUTICS

# Cara Therapeutics Pipeline

| Program | Indication* | STAGE OF DEVELOPMENT | | | | Commercialization Rights† (ex-Japan and S. Korea)‡ |
|---|---|---|---|---|---|---|
| | | Phase I | Phase II | Phase III | NDA Review | |
| **KORSUVA™ Injection** | Pruritus CKD-HD§ | FDA Priority Review | | | | US-Vifor EU / Other-VFMCRP‖ |
| **Oral KORSUVA™** | Pruritus AD | EOPII Meeting Q3 '21 | | | | Cara |
| **Oral KORSUVA™** | Pruritus NDD-CKD | | | | | Cara |
| **Oral KORSUVA™** | Pruritus PBC | | | | | Cara |
| **Oral KORSUVA™** | Pruritus NP | | | | | Cara |

*Cara Therapeutics has investigated KORSUVA™ for post-operative pain.
†Vifor has commercial rights in Non-US Fresenius Medical Care dialysis clinics under a profit-share arrangement.
‡Commercialization rights to KORSUVA™ in defined indications—Japan: Maruishi Pharma; South Korea: CKD Pharma.
§PDUFA date is August 23, 2021.
‖VFMCRP and Cara have rights to promote in Fresenius clinics in the US under a profit-share agreement.
CKD-HD: Chronic Kidney Disease-Hemodialysis; NDD—CKD: Non-Dialysis Dependent-Chronic Kidney Disease; AD: Atopic Dermatitis; PBC: Primary Biliary Cholangitis; NP: Notalgia Paresthetica.

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CARA THERAPEUTICS

# Oral KORSUVA[1] (Difelikefalin) NDD CKD-aP Next Steps

- Oral KORSUVA[1] (Difelikefalin) met the primary endpoint: 1mg dose advancement to Phase 3
  - Primary: Change from baseline in weekly mean WI-NRS score
  - Dose-dependent statistically significant improvement in Complete Responders
- Oral KORSUVA[1] (Difelikefalin) was generally well-tolerated: safety profile similar to Phase 3 Injection KORSUVA[1] (Difelikefalin) studies

**Plan to meet with the FDA in 4th Qtr., 2021 to discuss potential inclusion of earlier CKD patients in a Phase 3 program**


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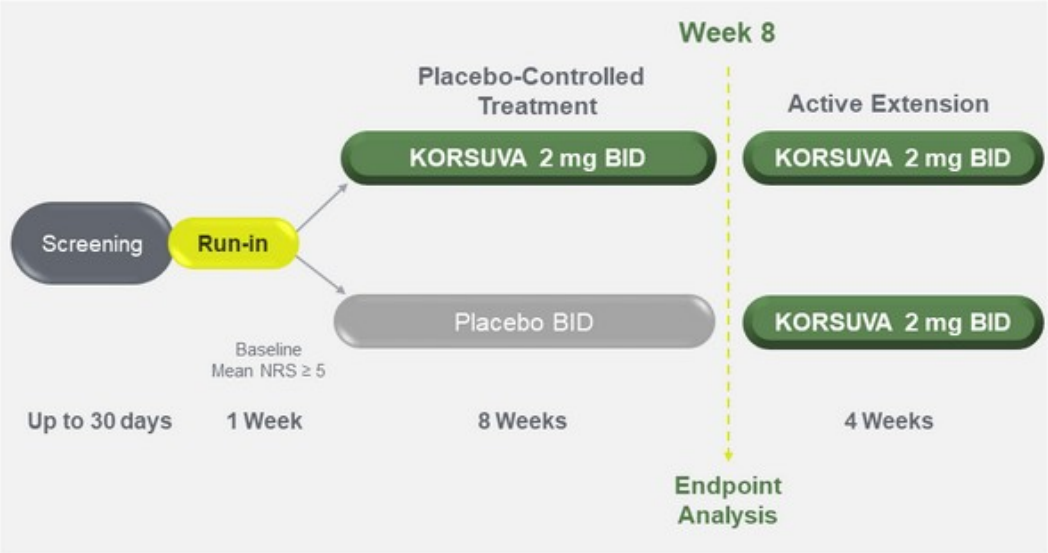
CARA THERAPEUTICS

# KOMFORT : Phase 2 Study in Notalgia Paresthetica




**Endpoints Week 8**

**Study:**
- ~120 adult patients with NP and moderate-to-severe pruritus

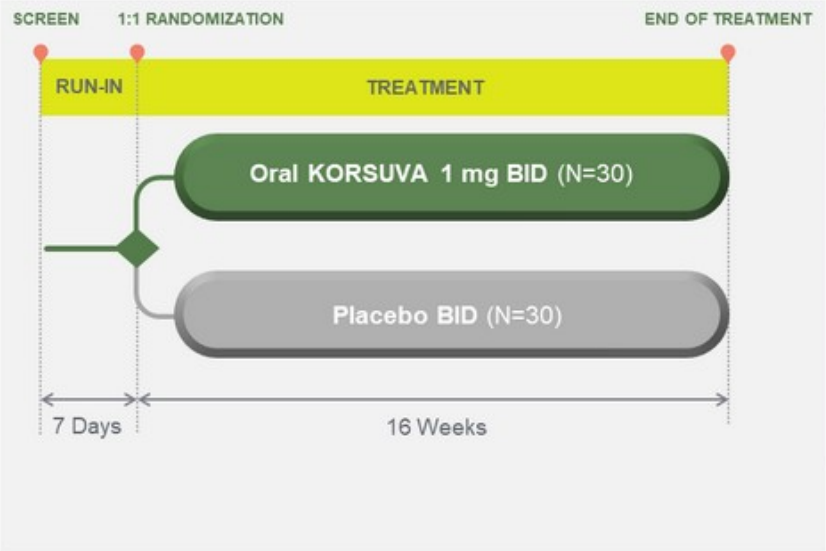
**Primary Endpoint:**
- Change from BL in weekly mean of daily 24-hr WI-NRS at week 8

**Other Endpoints:**
- QoL, Sleep, Responder Analyses, Safety



CARA THERAPEUTICS

# KLEAR: Phase 2 Study in Primary Biliary Cholangitis




**Endpoints Week 16**

**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
- Safety assessments



CARA THERAPEUTICS

# $207M Cash on hand June 30, 2021: Runway into 2023

***Forecast does not include KORSUVA[1] IV Approval Milestones & Profit***

**(AS OF JUNE 30, 2021)**

**Cash/marketable securities**
(Q2 2021)
**$207M**

**Shares outstanding:**
**~50.1M**

**Regulatory Milestones with IV Approval:**
**$65M USA & $15M EMA**

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# Projected Milestones–2021 & 2022




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