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) **March 11, 2022**

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	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 March 11, 2022, Cara Therapeutics, Inc. (the "Company") made available an updated corporate presentation, 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 (the "Exchange Act") or subject to the liabilities of that section, nor shall it be deemed to be incorporated by reference into any of the Company's filings with the Securities and Exchange Commission ("SEC") under the Exchange Act or the Securities Act of 1933, as amended, (the "Securities Act") whether made before or after the date hereof, regardless of any general incorporation language in such a filing. The information shall not be deemed incorporated by reference into any other filing with the SEC 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 March 11, 2022
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: March 11, 2022

Exhibit 99.1

Cara Therapeutics

CORPORATE PRESENTATION

MARCH 2022

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 forwardlooking statements include statements concerning the Company's ability to commercialize KORSUVA™(difelikefalin) injection, including the timing of additional regulatory submissions and approvals, the Company's ability to obtain and maintain coverage and adequate reimbursement for KORSUVA Injection, potential timeline for launch of KORSUVA injection, the potential timeline for post-TDAPA reimbursement, the potential of KORSUVA injection to be a therapeutic option for CKD-aP in dialysis dependent patients and the potential for KORSUVA to address additional pruritic indications, the performance of our commercial partners, including Vifor Pharma, expected timing of the initiation, enrollment and data readouts from the Company's planned and ongoing clinical trials, the potential results of ongoing clinical trials, timing of future regulatory and development milestones for 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 commercial launch, 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 Annual Report on Form 10-K for the year ended December 31, 2021 and its other documents subsequently filed with or furnished to the Securities and Exchange Commission. All forward-looking statements contained in this presentation 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.

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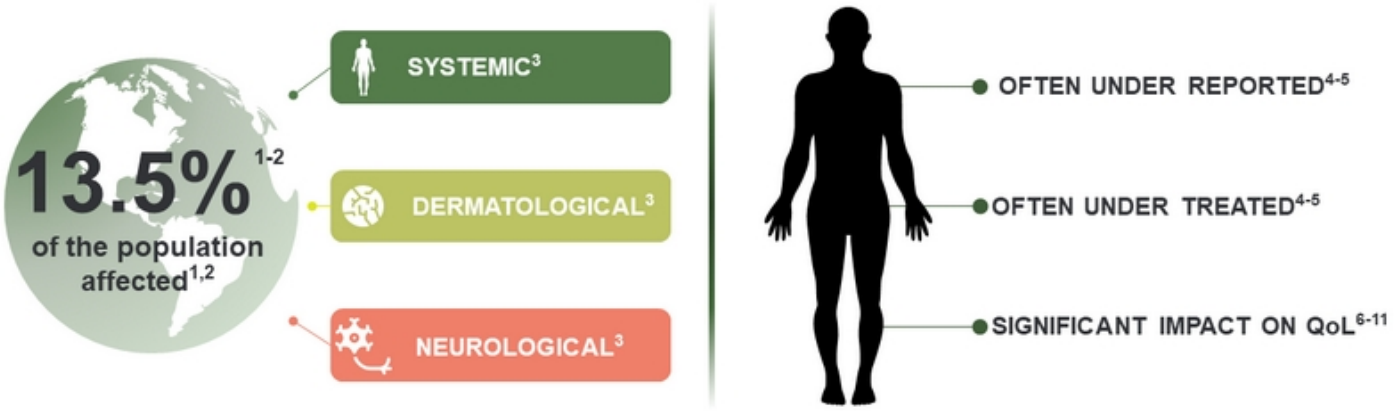
CARA THERAPEUTICS


OUR MISSION:
Transform the way pruritus is treated to bring quality to the lives of those who suffer.
CARA

About 1 in 8 people suffer from chronic pruritus



1. Matterne U. et al. Prevalence, correlates and characteristics of chronic pruritus: a population-based cross-sectional study. Acta Derm Venereol. 2011;91(6):674-9. 2. Matterne U et al. Incidence and determinants of chronic pruritus: a population-based cohort study. Acta Derm Venereol. 2013;93(5):532-7. 3. 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. 4. Rayner HC et al. *Clin J Am Soc Nephrol* 2017;12:2000-7. 5 Hegade VS et al. Pruritus Is Common and Undertreated in Patients With Primary Biliary Cholangitis in the United Kingdom. *Clinical Gastroenterology and Hepatology 2019* 6. Pisoni N et al. The course of chronic itch in hemodialysis patients: results of a 4-year follow-up study of GDHS (German Epidemiological Hemodialysis Itch Study). *J Eur Acad Dermatol Venereol.* 2019;33:1429-1435. 7. Mathur VS et al. A longitudinal study of uremic pruritus in hemodialysis patients. *Clin J Am Soc Nephrol.* 2010; 5:1410-1419. 8. Yosipovitch G et al. A questionnaire for the assessment of pruritus: validation in uremic patients. *Acta Derm Venereol.* 2001;81:108-111. 9. Rahman IU, et al. Prevalence of chronic kidney disease-associated pruritus, and association with sleep quality among hemodialysis patients in Pakistan. *PLoS One.* 2018;13:e0207758. 10. Pisoni RL et al. Pruritus in haemodialysis patients: international results from the Dialysis Outcomes and Practice Patterns Study (DOPPS). *Nephrol Dial Transplant.* 2006;21:3495-3505. 11. Ramakrishnan K et al. Clinical characteristics and outcomes of end-stage renal disease patients with self-reported pruritus symptoms. *Int J Nephrol Renovasc Dis.* 2014;7:1-12.

CARA THERAPEUTICS

Millions of US patients could benefit from a chronic pruritus therapy

		Estimated US Addressable Pruritis Population
SYSTEMIC	HD-Dependent Chronic Kidney Disease (CKD)[1-2]	200K
SYSTEMIC	Non-Dialysis Dependent CKD (Stage 4-5)[3-7]	300K
SYSTEMIC	Chronic Liver Disease[8-12]	3M
DERMATOLOGICAL	Atopic Dermatitis[13-15]	12M
NEUROLOGICAL	Notalgia Paresthetica[16]	1M

1.National Institute of Diabetes and Digestive and Kidney Diseases. https://www.niddk.nih.gov/health-information/health-statistics/kidney-disease. 2. Pisoni et al. Pruritus in haemodialysis patients: international results from the Dialysis Outcomes and Practice Patterns Study (DOPPS). Nephrology Dialysis Transplantation (2006); 21(12): 3495-3505. 3. Centers for Disease Control and Prevention https://nccd.cdc.gov/ckd/detail.aspx?Qnum=Q372. 4. DataMonitor 5. States Renal Data System https://adr.usrds.org/2020/chronic-kidney-disease/1-ckd-in-the-general-population. 6. Wong SJY et al. Decisions about Renal Replacement Therapy in Patients with Advanced Kidney Disease in the US Department of Veterans Affairs, 2000-2011. Clin Journal of Am Soc Nephrol. 2016. 11(10): 1825-1833. 7. Sukul N et al. Pruritus and patient reported outcomes in non-dialysis CKD. Clin J Am Soc Nephrol 2019. 673-681. 8.Centers for Disease Control and Prevention https://www.cdc.gov/nchs/fastats/liver-disease.htm 9. Odes S et al. Prevalence of pruritus in patients with chronic liver disease: A multicenter study. Hepatology Research. 2018. 28(3): E252-E262. 10. Fujino H et al. Pruritus in patients with chronic liver disease and serum autotaxin levels in patients with primary biliary cholangitis. BMC Gastroenterology. 2019. 19:169. 11. Yoshikawa et al. Pruritus is common in patients with chronic liver diseases and is improved by nalfurafine hydrochloride. Scientific Reports. 2021. 11:3015. 12. Data on file. 13. National Eczema Association. https://nationaleczema.org/eczema/types-of-eczema/atopic-dermatitis/ 14. DRG Analysis. 15. Mollanazar NK, Smith PK, Yosipovitch G. Mediators of chronic pruritus in atopic dermatitis: getting the itch out? Clin Rev Allergy Immunol. (2016) 51:263-92. 16. Data on file.

CARA THERAPEUTICS

Prepared for significant immediate and future growth

- First-and-only FDA-approved treatment for CKD-aP in HD
- Robust R&D engine with multiple pipeline indications
- Significant market opportunity & strong financial foundation to deliver growth strategy

CARA THERAPEUTICS

KORSUVA Injection to launch in US in April 2022

NOW APPROVED & COMING SOON

KORSUVA™ (difelikefalin) Injection

POSITIONED FOR RAPID UPTAKE

- FIRST-AND-ONLY PRODUCT APPROVED FOR CKD-aP in HD
- STRONG COMMERCIAL POSITIONING & PARTNERSHIP
- FIRST INNOVATIVE PRODUCT TO RECEIVE TDAPA

Korsuva is indicated for the treatment of moderate-to-severe pruritus associated with chronic kidney disease (CKD-aP) in adults undergoing hemodialysis (HD). Limitations of Use Korsuva has not been studied in patients on peritoneal dialysis and is not recommended for use in this population

CARA THERAPEUTICS

KORSUVA Injection addresses significant unmet need in US CKD-aP hemodialysis market

~500K
Patients on hemodialysis[1-2]

40%
With moderate-severe pruritus[2]

~200K
Addressable Market

1. National Institute of Diabetes and Digestive and Kidney Diseases. https://www.niddk.nih.gov/health-information/health-statistics/kidney-disease.
2. URSDS. https://adr.usrds.org/2021/end-stage-renal-disease/1-incidence-prevalence-patient-characteristics-and-treatment-modalities
3. Pisoni et al. Pruritus in haemodialysis patients: international results from the Dialysis Outcomes and Practice Patterns Study (DOPPS). Nephrology Dialysis Transplantation (2006); 21(12): 3495-3505.

CARA THERAPEUTICS

KORSUVA Injection first and only FDA approved therapy for CKD-aP in HD

NOW APPROVED & COMING SOON

KORSUVA™ (difelikefalin) Injection

First-and-Only FDA approved therapy to address **CKD-aP-HD**

- Current therapies are generally ineffective or poorly tolerated
- Breakthrough Therapy Designation
- Priority Review

Largest clinical development program for CKD-aP in HD with 1300 participants

Favorable safety profile

- Non-scheduled
- Most common AEs were diarrhea, dizziness, and nausea

CARA THERAPEUTICS

Concentrated market dynamics can facilitate rapid uptake

2 Key Providers

- **Fresenius Medical Care and DaVita have a combined market share of ~75%[1]**

1 Major Payer

- **Medicare covers ~80% of CKD-HD patients[2]**
- **2nd drug in TDAPA**
  - 1st drug Parsabiv - $1.4B revenue in 3-yr period[3]

1. https://healthcareappraisers.com/2020-outlook-dialysis-clinics-and-esrd/
2. https://adr.usrds.org/2020/end-stage-renal-disease/9-healthcare-expenditures-for-persons-with-esrd
3. Amgen Annual Report 2018, 2019, 2020

Partnership with Vifor Pharma can maximize launch potential

- Leading commercial nephrology organization with turnkey infrastructure, including 100+ sales FTEs
- Strong relationships with US nephrology offices and dialysis centers, including joint venture with Fresenius Medical Care
- Contractual economics bring near term profitability for KORSUVA Injection

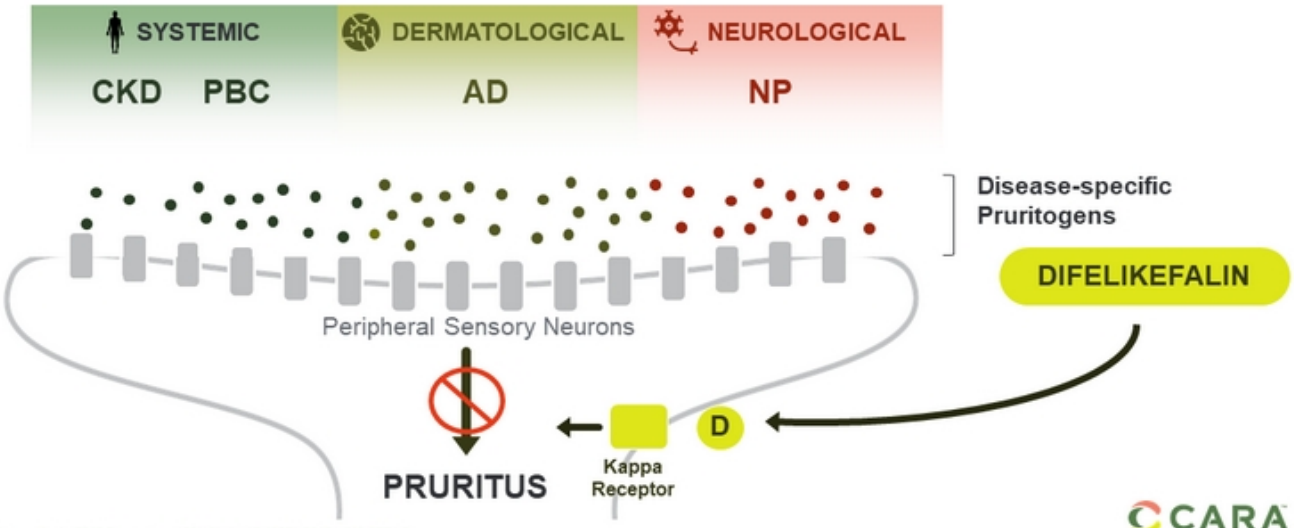
Favorable reimbursement for KORSUVA Injection

- Granted TDAPA and J-Code by CMS effective April 1, 2022
- TDAPA allows for KORSUVA to be billed separately from the ESRD bundle for at least two years
- CMS leadership to engage with Cara and Vifor Pharma ensuring patient access, including post-TDAPA

CARA THERAPEUTICS

Difelikefalin MOA has potentially broad application

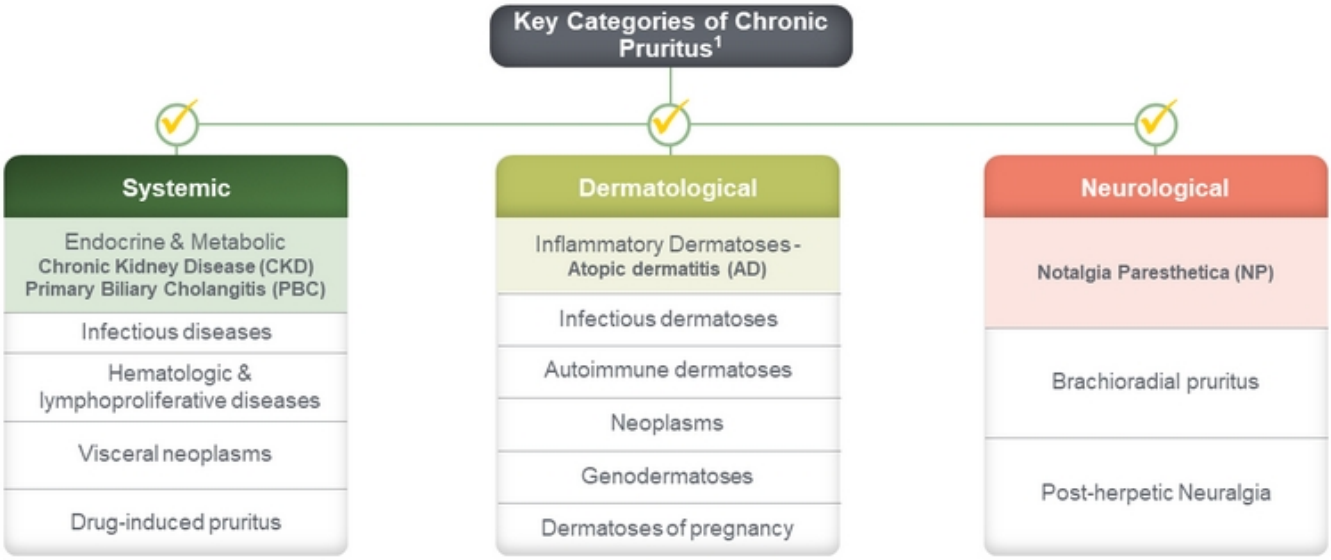
Difelikefalin blocks itch response agnostic of itch trigger



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

CARA THERAPEUTICS

Oral difelikefalin has potential for long-term growth



1. Matterne U. et al. Prevalence, correlates and characteristics of chronic pruritus: a population-based crosssectional study. Acta Derm Venereol. 2011;91(6):674-9.2. Matterne U et al. Incidence and determinants of chronic pruritus: a population-based cohort study. Acta Derm Venereol. 2013;93(5):532-7. 3. Adapted from: Stander S. et al. Clinical classification of itch: a position paper of the international forum for the study of itch. Acta Derm Venereol 2007. 87: 291-294.

CARA THERAPEUTICS

Advancing our late-stage pipeline in multiple indications

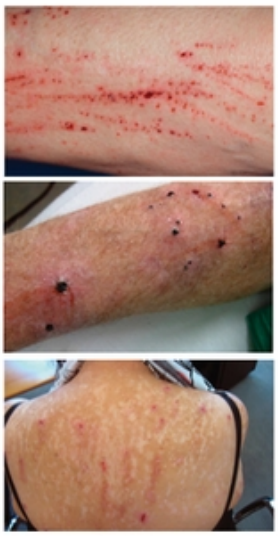
		STAGE OF DEVELOPMENT				
Program	Indication	Phase 1	Phase 2	Phase 3	Approved	Commercial Rights (ex-Japan and S. Korea)^
KORSUVA™ Injection	Pruritus HD-CKD					US- Vifor* EU/Other- VFMCRP#
Oral difelikefalin	Pruritus NDD-CKD (stages IV-V)					Cara
Oral difelikefalin	Pruritus in Atopic Dermatitis					Cara
Oral difelikefalin	Pruritus in NP					Cara
Oral difelikefalin	Pruritus PBC					Cara

^ Commercialization rights to difelikefalin in defined indications - Japan: Maruishi Pharmaceutical Co, LTD; South Korea: Chong Kun Dang Pharmaceuticals. # Vifor Fresenius Medical Care Renal Pharma (VFMCRP) and Cara have rights to promote in Fresenius Medical Care dialysis clinics in the US under a profit share agreement. * Vifor has commercial rights in Non-US Fresenius clinics under a profit-share arrangement. HD CKD-aP: Hemodialysis Chronic Kidney Disease-associated Pruritus; NDD-CKD-aP: Non-Dialysis Dependent Chronic Kidney Disease associated Pruritus

CARA THERAPEUTICS

Oral difelikefalin: expanding reach in non-dialysis CKD market

NDD-CKD

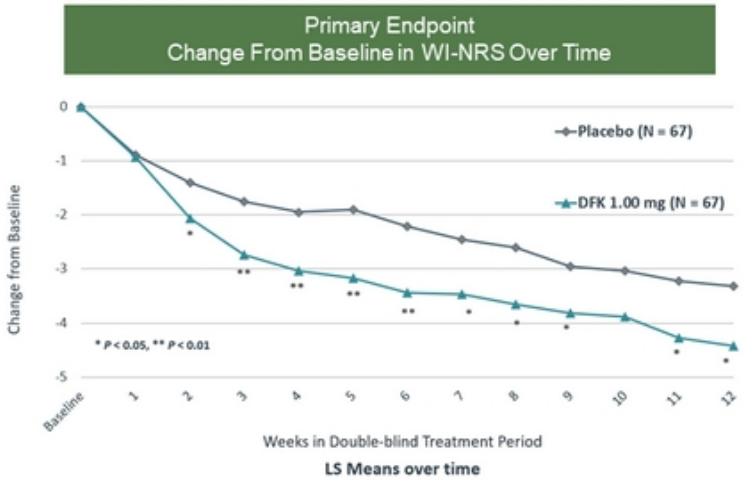


- **Pruritis control is a significant unmet need among non-dialysis CKD patients[1]**
- **There are no FDA-approved therapies and current anti-pruritic approaches are inadequate[1]**
- **Approximately 1.2 million US patients have advanced (stage 4-5) non-dialysis CKD[2-5]**
- **~30% advanced non-dialysis CKD patients experience moderate to severe pruritus[6]**

1. Makar M et al. Chronic kidney disease associated pruritus: a review. Kidney Blood Press Res 2021. 46:659-669. 2. Centers for Disease Control and Prevention https://nccd.cdc.gov/ckd/detail.aspx?Qnum=Q372. 3. DataMonitor 4. States Renal Data System https://adr.usrds.org/2020/chronic-kidney-disease/1-ckd-in-the-general-population. 5. Wong SJY et al. Decisions about Renal Replacement Therapy in Patients with Advanced Kidney Disease in the US Department of Veterans Affairs, 2000–2011. Clin Journal of Am Soc Neprol. 2016. 11(10): 1825-1833. 6. Sukul N et al. Pruritus and patient reported outcomes in non-dialysis CKD. Clin J Am Soc Neprhol 2019. 673-681. 7. Mettang T and Kremer AE. Uremic Pruritus. Kidney International. 2015. 87:685-691

CARA THERAPEUTICS

Phase 2 data in NDD-CKD-aP provides path forward into Phase 3



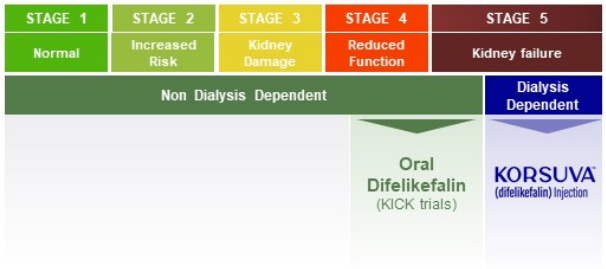
- ✓ **Significant difference achieved between 1mg oral difelikefalin and placebo in WI-NRS score at Week 12**
- ✓ **Generally well-tolerated with safety profile consistent with clinical development program**
- ✓ **Phase 2 findings and EOP2 discussion with FDA established dose and patient population in Advanced CKD for Phase 3 trial**

KICK 1 & KICK 2: Patient Population

NDD-CKD

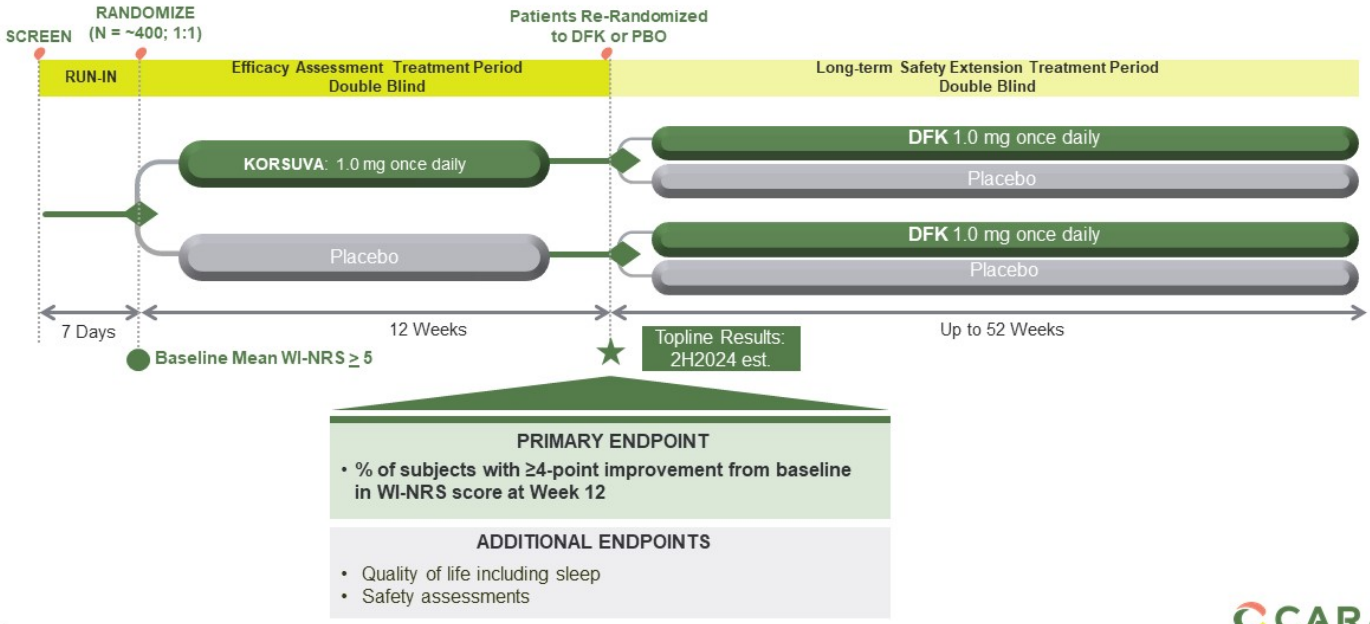
STUDY PATIENT POPULATION

- Adults with advanced stage 4 and 5 CKD
- Chronic Pruritus for at least 6 months prior to screening
- Moderate to Severe Pruritus at Baseline (WI-NRS ≥ 5)
- Allowed to be on stable treatment for itch including antihistamines and gabapentinoids



CARA THERAPEUTICS

KICK 1 & KICK 2: Study Design



PRIMARY ENDPOINT

- **% of subjects with ≥4-point improvement from baseline in WI-NRS score at Week 12**

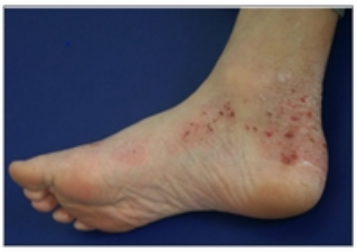
ADDITIONAL ENDPOINTS

- Quality of life including sleep
- Safety assessments

 KICK1 US sites only, KICK 2 US and ex-US sites

Oral difelikefalin: potential to address significant need for an oral antipruritic in atopic dermatitis (AD)

AD



Pruritus is a hallmark of AD, often called "the itch that rashes"[1]

Itch is considered the most burdensome AD symptom by patients,[2] strongly and negatively impacts quality of life[3]

~12M diagnosed patients that experience chronic pruritus[4-6]

Targeting pruritus in AD remains unmet need

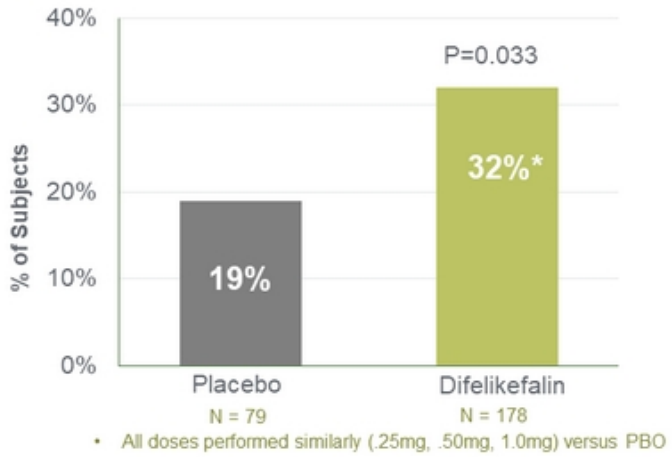
1. Correale CE et al. Atopic dermatitis: a review of diagnosis and treatment. Am Fam Physician. 1999. 60(4):1191-1198.2. Silverberg JI et al. Patient burden and quality of life in atopic dermatitis in US adults. Annals of Allergy, Asthma, and Immunology (2018). 121(3): 340-347 3. Legat FJ. Itch in atopic dermatitis – what is new? Front Med (Lausanne) 2021. 8:644760. 4. National Eczema Assocaition. https://nationaleczema.org/eczema/types-of-eczema/atopic-dermatitis/ 5. DRG Analysis. 6. Mollanazar NK, Smith PK, Yosipovitch G. Mediators of chronic pruritus in atopic dermatitis: getting the itch out? *Clin Rev Allergy Immunol.* (2016) 51:263–92. 7. Lipman et al. Current clinical options for the management of itch in atopic dermatitis. Clin Cosmet Investig Dermatol. 2021. 14:959-969 8. Kapur S et al. Atopic dermatitis. Allergy Asthma and Clin Immunol. 2018. 14(Suppl2):52.

CARA THERAPEUTICS

AD

KARE STUDY: Phase 2 data in Atopic Dermatitis (AD)

Population: Mild to Moderate AD (BSA <10)
4-point Responder Analysis at Week 12



- All doses performed similarly (.25mg, .50mg, 1.0mg) versus PBO

- ✓ **Anti-pruritic effect started at week 1 and was sustained through week 12**
- ✓ **Statistical significance achieved for the registration endpoint (4-point responder) in mild-to-moderate AD population**
- ✓ **The drug was generally well tolerated**

CARA THERAPEUTICS

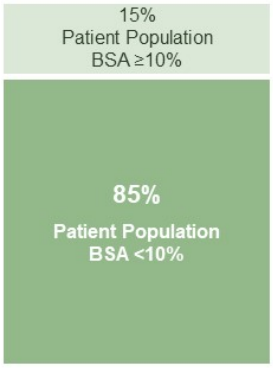
KIND 1 & KIND 2: Patient Population

AD

STUDY PATIENT POPULATION

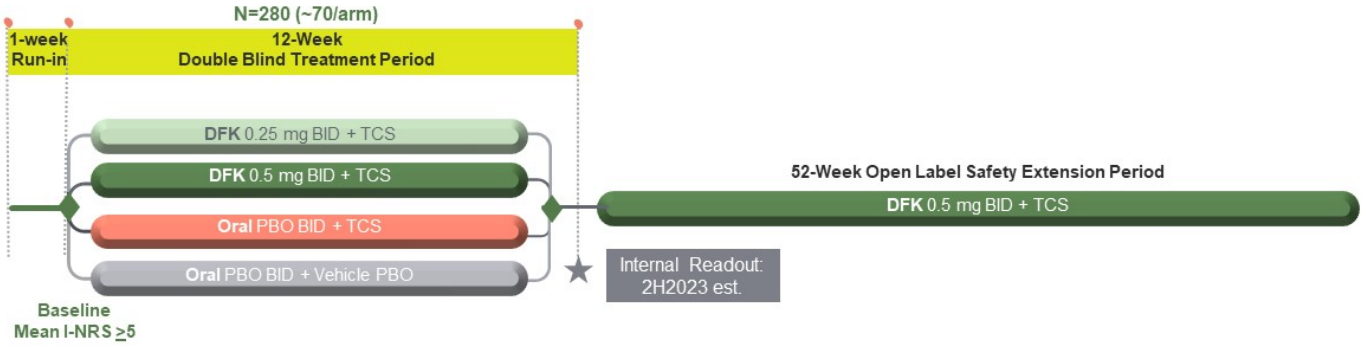
- Adults with AD-related pruritus not adequately controlled by topical therapy alone
- Chronic AD-related Pruritus ≥6 weeks
- Moderate to Severe Pruritus at Baseline (I-NRS ≥ 5)
- Mild to severe Atopic Dermatitis:
  - IGA ≥ 2, BSA ≤20%
- Patients need to be washed out of any medication that may impact itch and/or AD prior to screening
- Stratification to BSA <10% and ≥10%

Target Enrollment



CARA THERAPEUTICS

KIND 1 Part A: Study Design



CRITERIA

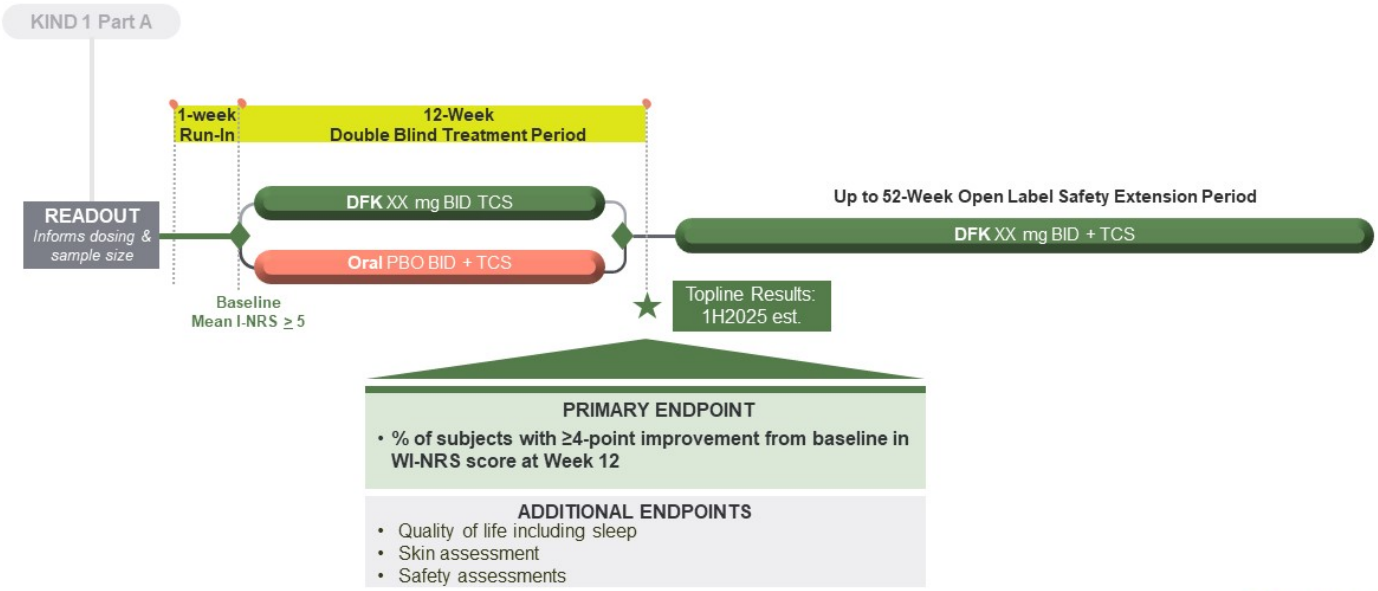
- % of subjects with ≥4-point improvement from baseline in WI-NRS score at Week 12
- Safety assessments

INFORMATION

- Dose
- Sample size

KIND 1 Part A will include sites in North America only

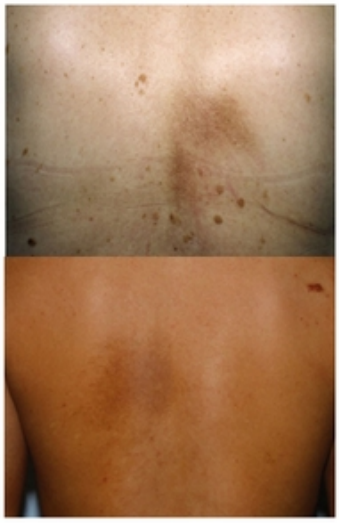
KIND 1 Part B & KIND 2: Study Design



 KIND 1 Part B will include sites in North America only, while KIND 2 will include sites in North America and outside of North America

Oral difelikefalin: potential to address significant need in Notalgia Paresthetica (NP)

NP



- **NP is a sensory neuropathic syndrome characterized by chronic pruritus**
- **Pruritus is burdensome decreasing quality of life[1]**
- **Estimated that 1M patients suffer from NP[2]**
- **No FDA-approved treatments**

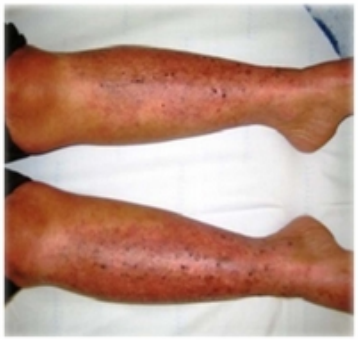
Phase 2 Readout Anticipated Q2 2022

 | 1. Howard M et al. Notalgia paresthetica: a review for dermatologists. Int J of Derm. 2017. 388-392. 2. Data on file.

CARA THERAPEUTICS

Oral difelikefalin: potential in pruritus with Primary Biliary Cholangitis (PBC)

PBC



- **Pruritus is hallmark symptom of PBC and may be persistent and debilitating[1]**
- **Associated with severe fatigue, sleep disturbance, and mental health issues[2]**
- **Addressable patient population of ~50K[3-4], with opportunity to establish efficacy in other chronic liver diseases**
- **No FDA-approved treatments**

Phase 2 Readout Anticipated 2H 2022

1. Carrion AF et al. Understanding and treating pruritus in primary biliary cholangitis. Clin Liver Dis 2018. 22:517-532. 2. Pinheiro NC et al. Refractory pruritus in primary biliary cirrhosis. BMJ Case Rep. 2013. doi:10.1136/bcr-2013-200634 3. Lu M et al. Factors Associated with Prevalence and Treatment of Primary Biliary Cholangitis in United States Health Systems. Clin Gastroenterol Hepatol (2018 Aug);16(8):1333-1341.e6. 4. Trivedi HD et al. Management of Pruritus in Primary Biliary Cholangitis: A Narrative Review. The American Journal of Medicine (2017) 130, 744e1-744e7

CARA THERAPEUTICS

Strong financial foundation to advance pipeline, enable long-term growth

Cash runway through 2023

- Runway does not include potential near term income from KORSUVA Injection profit split or commercial/regulatory milestones
- Contractual economics bring near term profitability on KORSUVA Injection

$237M cash position Dec 31, 2021

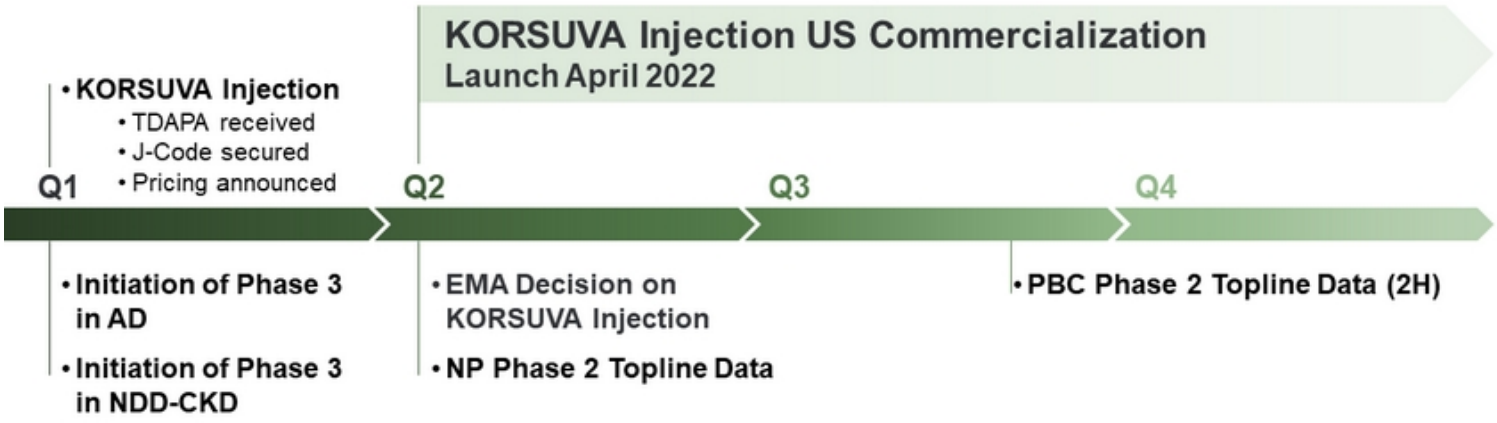
- 53M shares outstanding and no debt
- We do not expect to incur commercial costs related to KORSUVA Injection

Continued pipeline growth

- We have the resources to continue development of the oral difelikefalin program

CARA THERAPEUTICS

2022 Value Catalysts to Drive Long-term Growth*



*Anticipated Timelines

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THANK YOU