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 7, 2023**

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 August 7, 2023, 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, 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 August 7, 2023
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/ CHRISTOPHER POSNER
Christopher Posner
Chief Executive Officer

Date: August 7, 2023

Exhibit 99.1

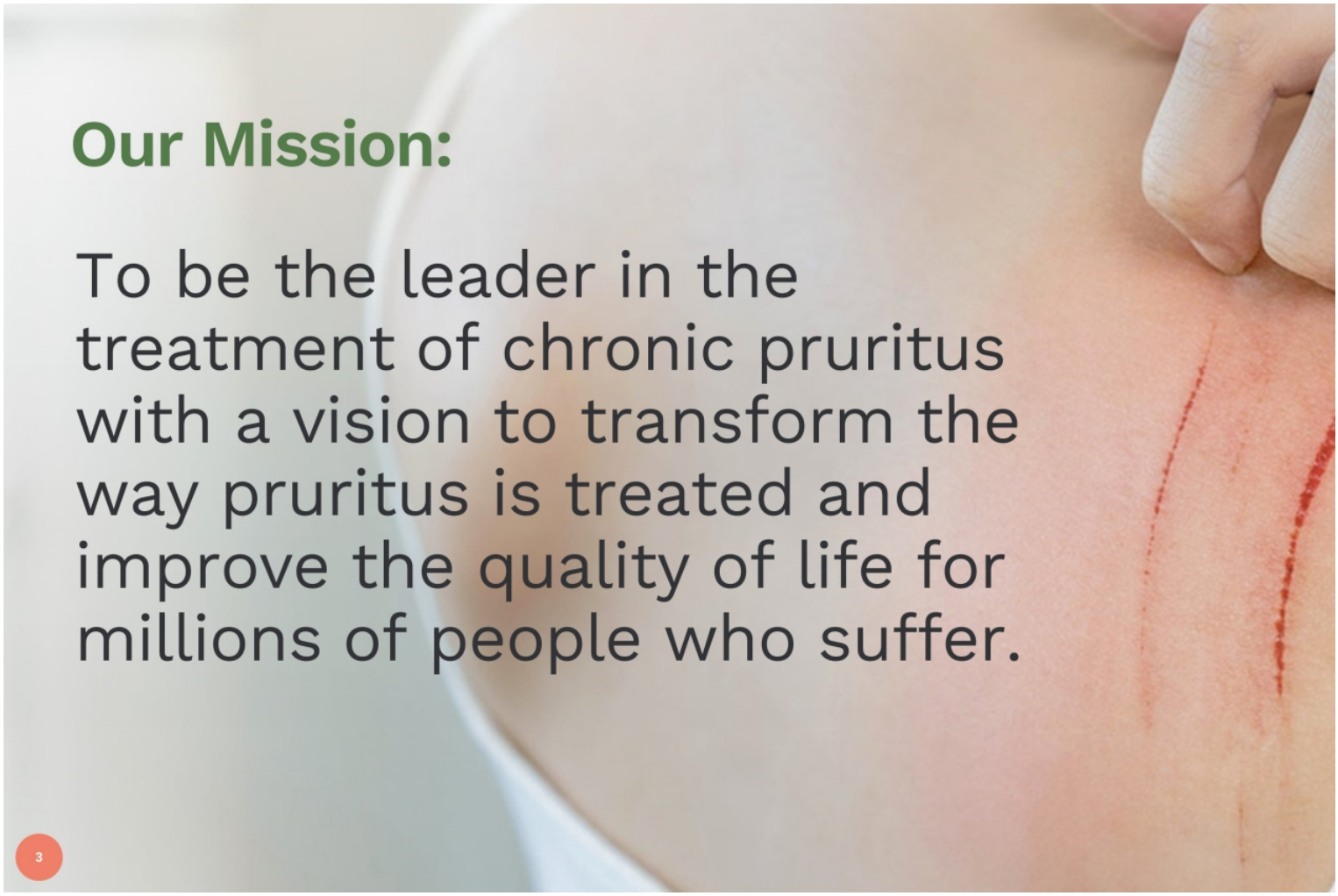
CARA THERAPEUTICS

Corporate Presentation

August 2023

Forward-Looking Statements

Statements contained in this presentation regarding matters that are not historical facts are "forward-looking statements meaning of the Private Securities Litigation Reform Act of 1995. Examples of these forward-looking statements include s concerning the Company's ability to successfully commercialize KORSUVA injection and Kapruvia, future revenue and pro sales of KORSUVA and Kapruvia, planned future regulatory submissions and potential future regulatory approvals, potent TDAPA reimbursement of KORSUVA and timing of final rules related thereto, future product launches, the performance o commercial partners, including CSL Vifor, expected timing of the initiation, enrollment and data readouts from the Compa and ongoing clinical trials, the potential results of ongoing clinical trials, timing of future regulatory and development mile Company's product candidates, the potential for the Company's product candidates to be alternatives in the therapeutic a investigated and the potential for oral difelikefalin to address additional pruritic indications, the size and growth of the pot for pruritus management, and the Company's expected cash reach. Because such statements are subject to risks and un actual results may differ materially from those expressed or implied by such forward-looking statements. These risks and include the risks inherent in the launch of new products, including that our commercial partners, including CSL Vifor, may expected, risks inherent in the clinical and regulatory development of pharmaceutical products, and the risks described m Therapeutics' filings with the Securities and Exchange Commission, including the "Risk Factors" section of the Company' on Form 10-K for the year ending December 31, 2022 and its other documents subsequently filed with or furnished to the Exchange Commission, including its Form 10-Q for the quarter ended June 30, 2023. All forward-looking statements contai presentation speak only as of the date on which they were made. Cara Therapeutics undertakes no obligation to update s to reflect events that occur or circumstances that exist after the date on which they were made, except as required by law


Our Mission:
To be the leader in the treatment of chronic pruritus with a vision to transform the way pruritus is treated and improve the quality of life for millions of people who suffer.
3

Difelikefalin, a Pipeline in a Product

Novel, first-in-class selective and potent kappa opioid receptor agon

Unique Chemical Structure and Features

- Synthetic peptide made of non-natural amino acids
- High hydrophilicity, high polar surface area and charge at physiological pH
- Does not readily cross the blood-brain-barrier

1

Differentiated MOA

- Acts on KORs on peripheral terminals of senso and immune cells
- Works downstream potentially as broad spectr antipruritic

Attractive Pharmacology

- Highly selective and potent full agonist at KORs
- Does not produce classical mu opioid side effects (e.g., euphoria, addiction and respiratory depression)
- **Non-scheduled drug**

2

Strong Clinical Data in Multiple Thera

- IV formulation approved for chronic kidney dis pruritus (CKD-aP) in hemodialysis patients
- Oral formulation has shown positive clinical da treatment of chronic pruritus
  - Advanced CKD
  - Atopic Dermatitis
  - Notalgia Paresthetica

Strategic Focus on Moderate to Severe Chronic Pruritu

NEPHROLOGY

Advanced CKD Hemodialysis

APPROVED

~ 200K patients undergoing hemodialysis (HD) suffer from moderate-to-severe chronic pruritus

KORSUVA injection is the first-and-only FDA approved product to help these patients.

Advanced CKD Pre-Dialysis

PHASE 3

~ 300K patients with stage 4-5 advanced CKD suffer from moderate-to-severe chronic pruritus

There are no approved therapies.

DERMATOLOGY

Atopic Dermatitis

PHASE 3

~ 3M mild-to-moderate patients with Atopic Dermatitis (AD) suffer from moderate-to-severe chronic pruritus

Chronic pruritus is one of the defining features of AD.

Notalg Parest

PHAS

~ 650K pa Notalgia P are in the healthcar moderate- chronic pr

There are therapies.

KORSUVA® Injection Launch Underway

KORSUVA®
(difelikefalin) Injection

First-and-only product approved for CKD-aP in HD in countries worldwide*

- US launch in 2Q22
- EU launch (Kapruvia) in 2H22
- AU, CA, SA, SG approvals in 2H22 – launches planned
- JP approval expected 2H23

CSL Vifor

Strong Commercial Partnership with Favorable Economics

- Leading commercial nephrology organization with 100+ sales FTEs in US
- Strong relationships with US nephrology offices and dialysis centers
- Joint venture with Fresenius Medical Care* *

Only Current Prod TDAPA Designatio

- Concentrated pa with ~80% Medic
- Reimbursed at A minimum of two
- ESRD PPS CY24 expected 4Q23 t post-TDAPA reim

* Other countries where Korsuva/Kapruvia has been approved include Austria, Australia, Belgium, Bulgaria, Canada, Croatia, Cyprus, Czech Rep., Denmark, Estonia, Finland, France, Germany, Greece, Hungary, Iceland, Ireland, Israel, Italy, Kuwait, Latvia, Liechtenstein, Lithuania, Luxembourg, Malta, The Netherlands, Norway, Poland, Portugal, Romania, Slovakia, Slovenia, Spain, Sweden, United Kingdom, Switzerland, Singapore, and United Arab Emirates.

** Vifor has contracted the sales force of Fresenius Renal Pharmaceuticals, a division of Fresenius Medical Care North America, to complement its sales force in selling into Fresenius clinics in the U.S.

NOTE: 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

Oral Difelikefalin: Expanding Reach in Advanced CKD-aP Market

Pruritis control is a significant unmet need among advanced CKD patients[1]

There are no FDA-approved therapies and current anti-pruritic approaches are inadequate[1,2]

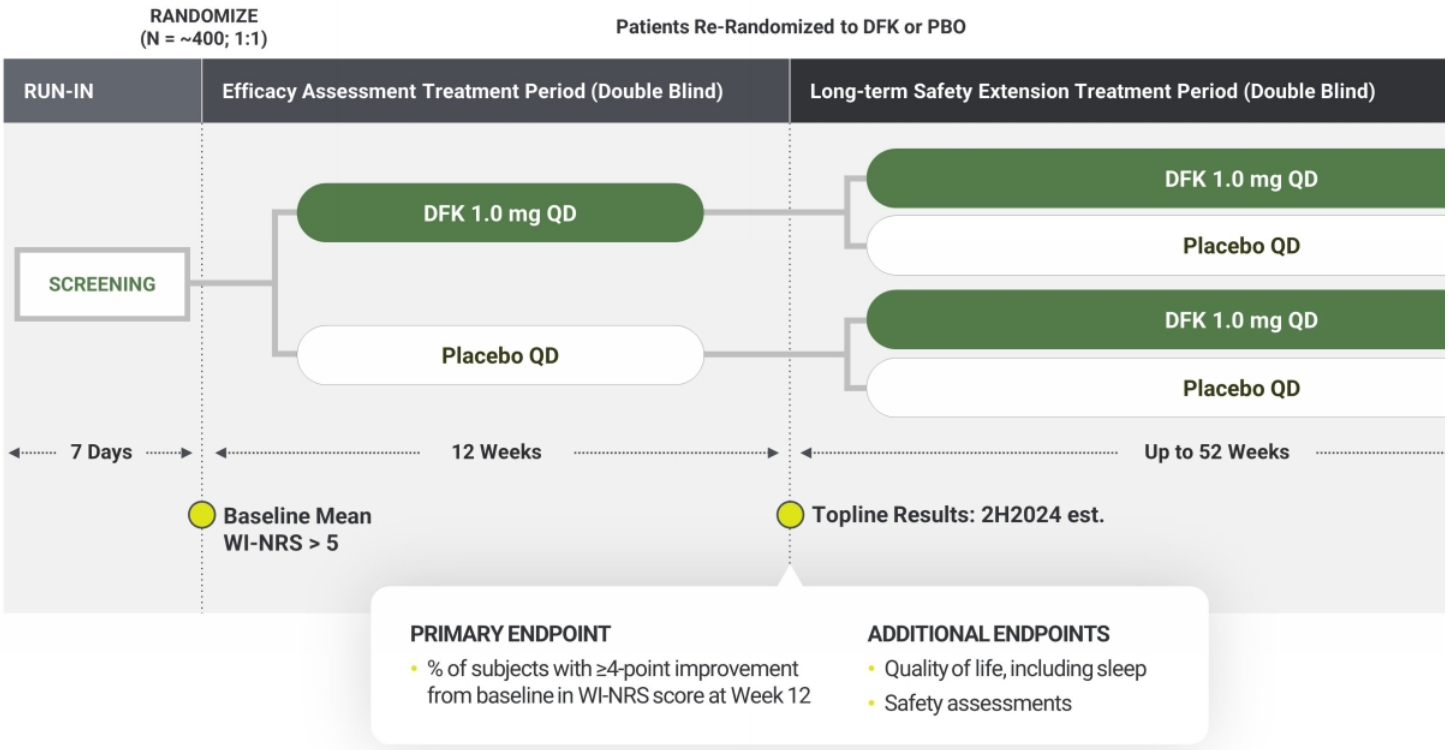
Approximately 1.2 million US patients have advanced (stage 4-5) non-dialysis CKD[3-6]

~30% advanced CKD patients experience moderate to severe pruritus[7]

1. Makar M et al. Chronic kidney disease associated pruritus: a review. Kidney Blood Press Res 2021. 46:659-669. 2. Mettang T and Kremer AE. Uremic Pruritus. Kidney International. 2015. 87:685-691 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 Neprol. 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.

KICK 1 & KICK 2: Phase 3 Study Design in CKD

Program initiated in 1Q22, enrollment ongoing



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

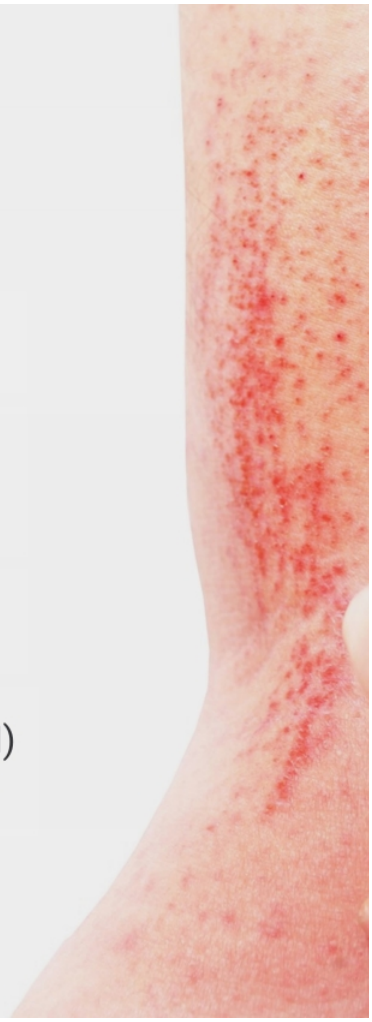
Oral Difelikefalin: Potential to Address Significant Need for an Oral Antipruritic in Atopic Dermatitis (AD)

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]

Pruritus in AD remains an unmet need

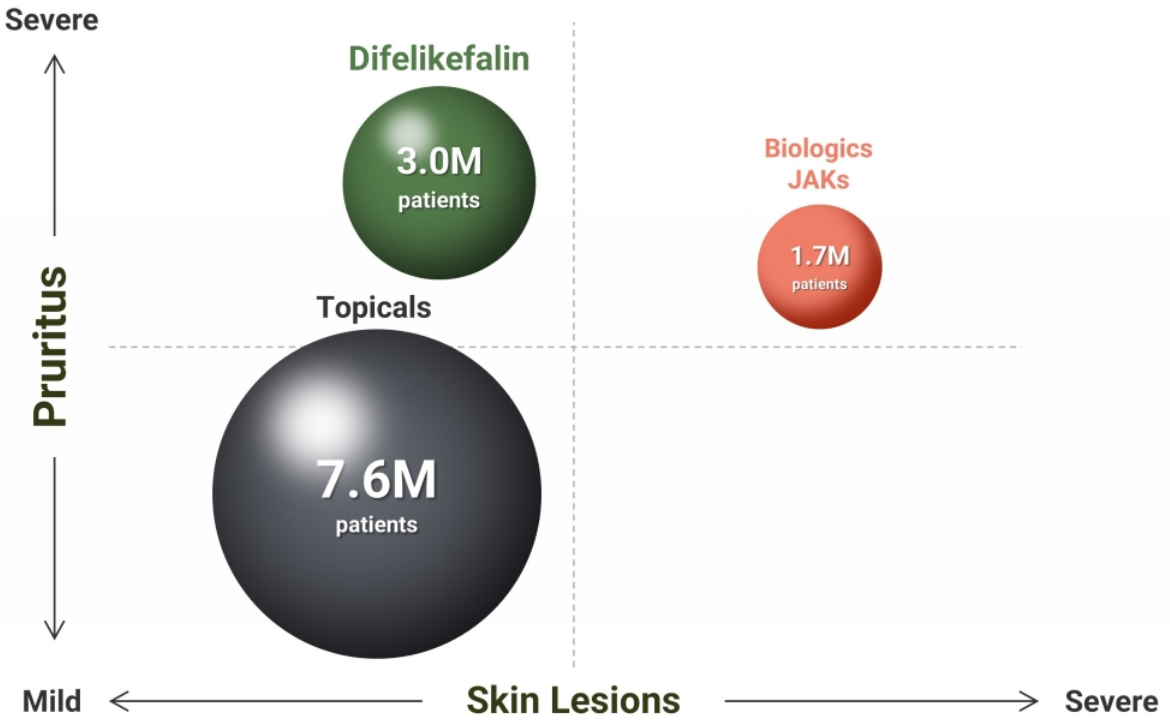
Target “itch dominant” adult AD patients (~25% of market or ~3M) with moderate to severe pruritus, but mild to moderate disease[4-6]



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. Barbarot S, Auziere S, Gadkari A, et al. Epidemiology of atopic dermatitis in adults: results from an international survey. Allergy. 2018;73(6):1284-1293. 5. United States Census Bureau 2020. 6. Raj Chovatiya MD, PhD , Donald Lei MS , Adnan Ahmed BS, Rajeev Chavda MD, Sylvie Gabriel MD, Jonathan I. Silverberg MD, PhD, MPH , Clinical phenotyping of atopic dermatitis using combined itch and lesional severity: A prospective observational study, Annals of Allergy, Asthma Immunology (2021).

Oral Difelikefalin: Targeting Itch Dominant Adult AD M

Differentiated positioning in a seemingly crowded market

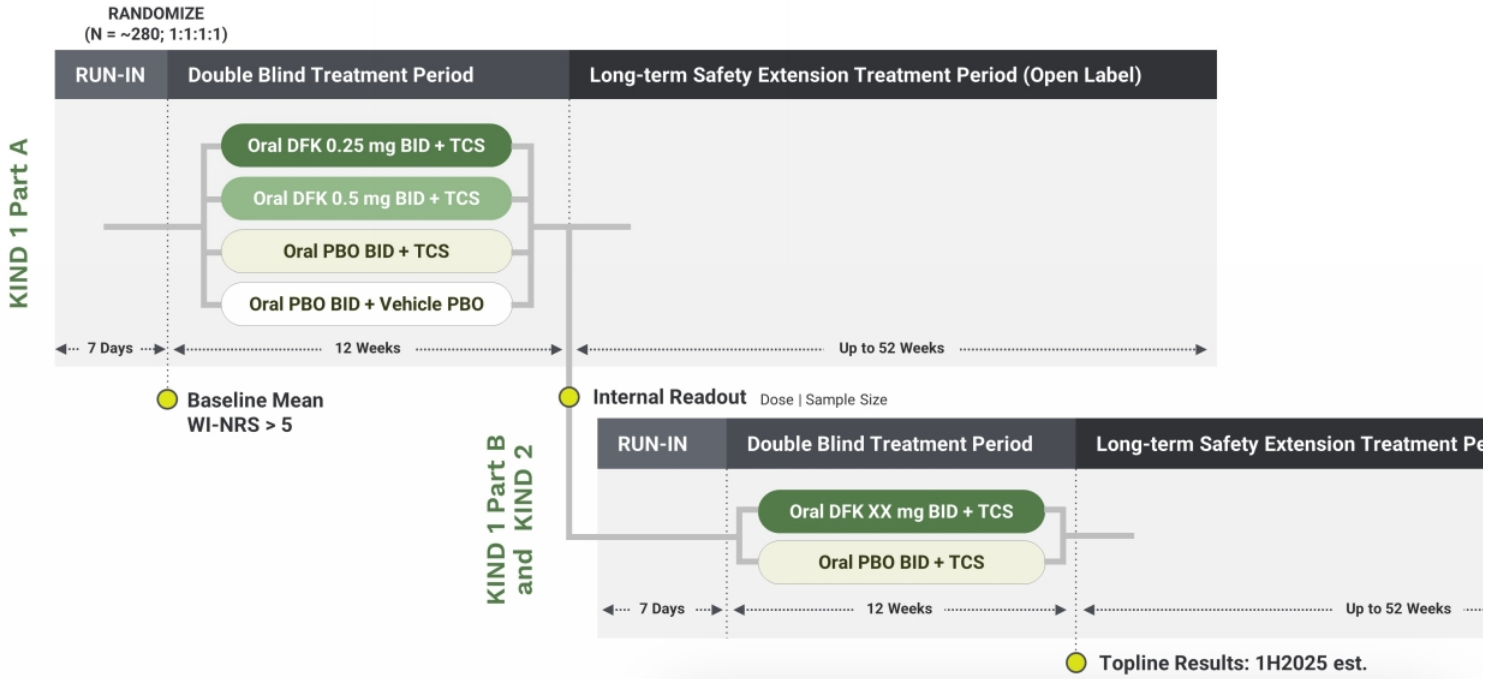


- **Itch Dominar**
  Significant U
  Patients with
  moderate les
  moderate to
- **Sizeable Tar**
  12M adult AD
  80% mild-mo
  30% modera
- **Preferable P**
  Characteristi
  Oral, non-ste
  biologic thera

1. Raj Chovatiya MD, PhD , Donald Lei MS , Adnan Ahmed BS, Rajeev Chavda MD, Sylvie Gabriel MD, Jonathan I. Silverberg MD, PhD, MPH , Clinical phenotyping of atopic dermatitis using combined itch and lesional severity: A prospective observational study, Annals of Allergy, Asthma Immunology (2021).

KIND 1 & KIND 2: Phase 3 Study Design in AD

Program initiated in 1Q22, enrollment ongoing



PRIMARY ENDPOINT

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

ADDITIONAL ENDPOINTS

- Quality of life, including sleep
- Skin assessment
- Safety assessments

KIND 1 Part A will include sites in USA only

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 is a sensory neuropathic syndrome characterized by chronic pruritus[1]

Pruritus is burdensome and impairs quality of life[2]

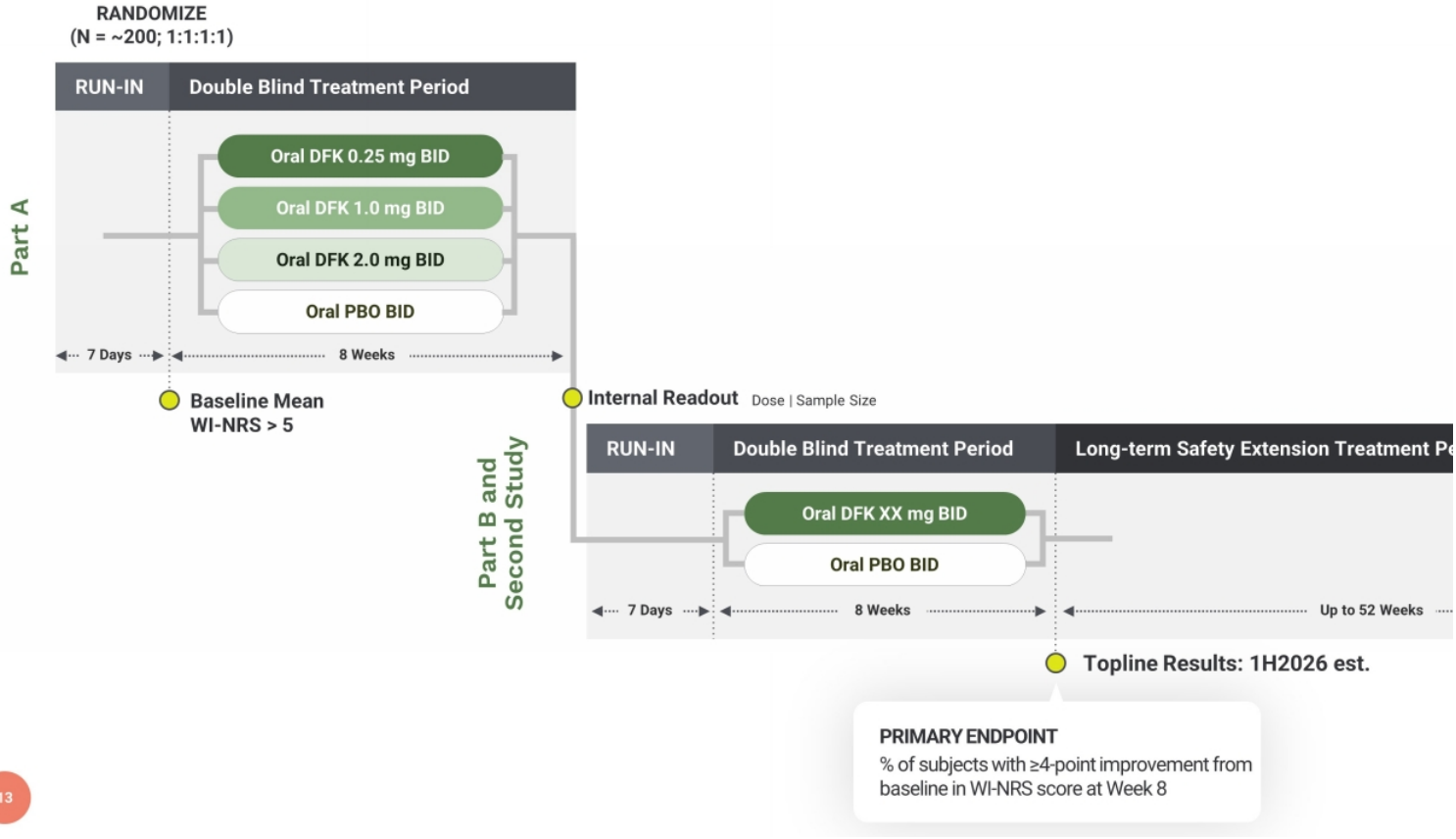
Estimated >650K patients currently treated for NP[1, 3-5]

No FDA-approved treatments; off label treatments are either ineffective or have tolerability issues[2]

1. Pereira P. et al., Acta DV 2018 ; 98:82-88; 2. Howard M et al. Notalgia paresthetica: a review for dermatologists. Int J of Derm. 2017. 388-392. 3. US Census Bureau 2020 population projection; 4. Mollanazar N.K. et al., Acta Clin Croat 2018; 57:721-725; 5. Syneos Health qualitative primary research of US dermatologists, Feb 2022; 5. Syneos market research and Apollo claims database

Phase 2/3 Study Design in NP

Program initiated in 1Q23



Catalysts to Drive Long-term Growth*

Initiation
KOURAGE 1 Part A
NP Phase 2/3
(1Q 2023)

KIND 1 Part A
AD Phase 3
Internal Readout
(4Q 2023)

KORSUVA approval
Japan
(2H 2023)

KICK 1 & 2
Advanced CKD Phase 3
Topline Data
(2H 2024)

KOURAGE 1 Part A
NP Phase 3
Internal Readout
(2H 2024)

KIND 1B & 2
AD Phase 3
Topline Data
(1H 2025)

KORSUVA® Injection US Commercialization - Launched April 2022

Kapruvia/KORSUVA International Commercialization - Launched September 2022

2023 2024 2025 202

*Anticipated Timelines

Strong Financial Foundation to Advance Pipeline Drive Long-term Growth

1 **Cash runway for at least next 12 months**

2 **$102M cash position as of June 30, 2023**

- 54M shares outstanding and no debt
- Cara has no cash outlay for commercial costs related to Korsuva/Kapruvia Injection

3 **Continued pipeline growth**

- Sufficient resources to continue development of the oral difelikefalin platforms

CARA THERAPEUTICS

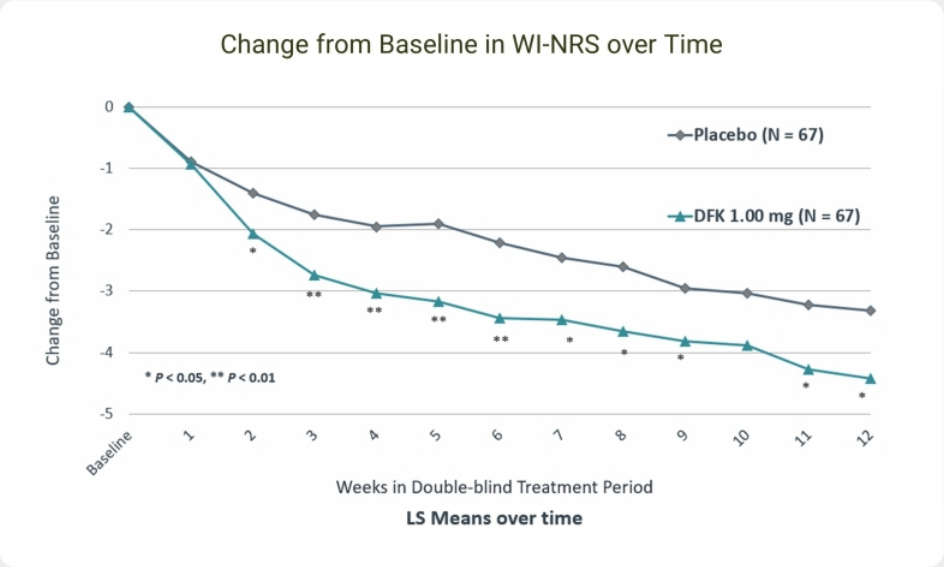
Thank You

CARA THERAPEUTICS

Appendix

Phase 2 Data Provides Path Forward into Phase 3 Advanced CKD

Primary Endpoint



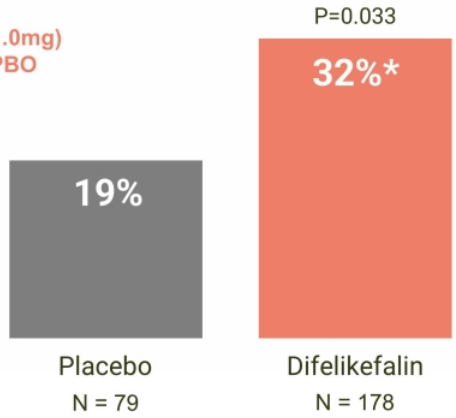
- Significant difference ach between 1mg oral difelike placebo in WI-NRS score
- Generally well-tolerated w profile consistent with cli development program
- Phase 2 findings and EOP discussion with FDA esta and patient population in CKD for Phase 3 trial

KARE STUDY: Phase 2 Data in Atopic Dermatitis (

Population: Mild to Moderate AD (BSA <10)

4-point Responder Analysis at Week 12
(% of Subjects)

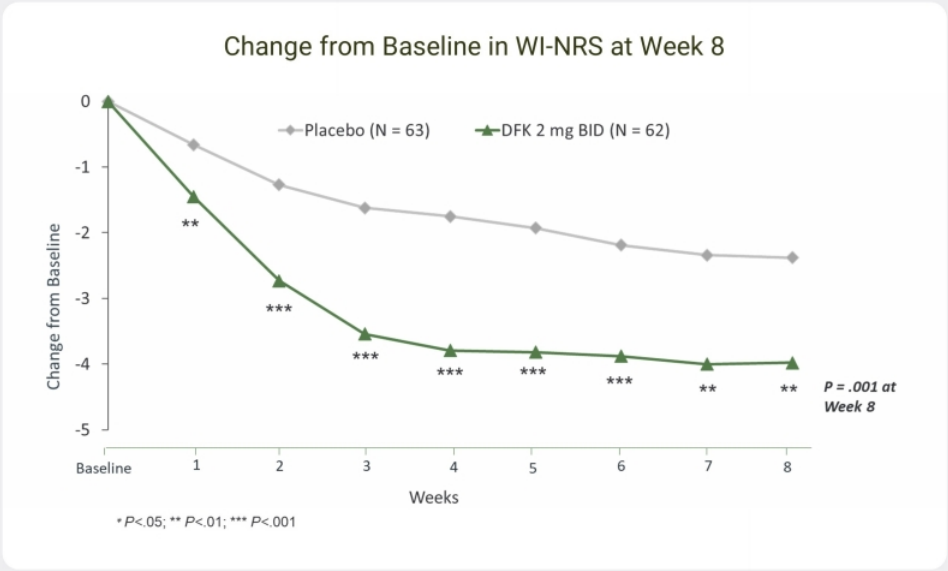
All doses (0.25mg, 0.50mg, 1.0mg) performed similarly versus PBO



- Anti-pruritic effect started and was sustained throug
- Statistical significance ac the registration endpoint (responder) in mild-to-moc population
- The drug was generally w

Encouraging Phase 2 Data in First Well-Controlle NP Study

Primary Endpoint



- Significant difference ach 2 mg BID oral difelikefalin in WI-NRS score at Week
- Rapid onset of action with sustained response throu
- Significantly greater prop patients on difelikefalin w improvement starting We
- Generally well-tolerated w profile consistent with oth development programs

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