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 23, 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 **107 Elm Street, 9th Floor** **Stamford, Connecticut** (Address of principal executive offices)	**06902** (Zip Code)

Registrant's telephone number, including area code: **(203) 406-3700**

Check the appropriate box below if the Form 8-K filing is intended to simultaneously satisfy the filing obligation of the registrant under any of the following provisions (*see* General Instruction A.2.):

☐ Written communications pursuant to Rule 425 under the Securities Act (17 CFR 230.425)

☐ Soliciting material pursuant to Rule 14a-12 under the Exchange Act (17 CFR 240.14a-12)

☐ Pre-commencement communications pursuant to Rule 14d-2(b) under the Exchange Act (17 CFR 240.14d-2(b))

☐ Pre-commencement communications pursuant to Rule 13e-4(c) under the Exchange Act (17 CFR 240.13e-4(c))

Securities registered pursuant to Section 12(b) of the Act:

Title of each class	Trading Symbol(s)	Name of each exchange on which registered
Common stock, par value $0.001 per share	CARA	The Nasdaq Stock Market LLC

Indicate by check mark whether the registrant is an emerging growth company as defined in Rule 405 of the Securities Act of 1933 (§230.405 of this chapter) or Rule 12b-2 of the Securities Exchange Act of 1934 (§240.12b-2 of this chapter).

Emerging growth company ☐

If an emerging growth company, indicate by check mark if the registrant has elected not to use the extended transition period for complying with any new or revised financial accounting standards provided pursuant to Section 13(a) of the Exchange Act. ☐

Item 8.01 Other Information.

On August 23, 2021, Cara Therapeutics, Inc. issued a press release announcing that the US Food and Drug Administration has approved its New Drug Application for KORSUVA™ injection for the treatment of moderate-to-severe pruritus in hemodialysis patients. A copy of the press release is attached as Exhibit 99.1 to this Current Report on Form 8-K and incorporated herein by reference.

Item 9.01 Financial Statements and Exhibits.

(d) Exhibits

Exhibit No.	
99.1	Press Release dated August 23, 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 23, 2021

Press Release	**Cara Therapeutics and Vifor Pharma announce U.S. FDA approval of KORSUVA™ (difelikefalin) injection for the treatment of moderate-to-severe pruritus in hemodialysis patients**

- **First and only therapy approved by the FDA for the treatment of pruritus associated with chronic kidney disease (CKD-aP) in adults undergoing hemodialysis**
- **Promotional launch of KORSUVA™ injection in the U.S. is expected in Q1 2022, with reimbursement in H1 2022**
- **Company to host conference call today at 5.00 p.m. ET**

Stamford, Conn. and St. Gallen, Switzerland, 23 August 2021 – Cara Therapeutics (Nasdaq: CARA) and Vifor Pharma today announced that the U.S. Food and Drug Administration (FDA) has approved KORSUVA™ (difelikefalin) for injection for the treatment of moderate-to-severe pruritus associated with chronic kidney disease in adults undergoing hemodialysis . KORSUVA™ injection is a first-in-class kappa opioid receptor (KOR) agonist that targets the body's peripheral nervous system. The KORSUVA™ injection new drug application (NDA) received Priority Review by the FDA, which is granted to therapies that, if approved, would offer significant improvements in the safety or effectiveness of the treatment, diagnosis, or prevention of serious conditions when compared to standard applications.

"The FDA approval of KORSUVA™ injection is a transformational milestone for Cara and a significant advancement for the substantial number of adult hemodialysis patients suffering from moderate-to-severe pruritus," said Derek Chalmers, Ph.D., D.Sc., President and Chief Executive Officer of Cara Therapeutics. "We look forward to working closely with our commercial partner, Vifor Pharma, to launch KORSUVA™ injection in the U.S in the coming months. We extend our deepest gratitude to the patients who participated in our KALM-1 and KALM-2 clinical trials, the study investigators, and especially our employees, as their commitment through over 10 years of collective effort made this important milestone possible."

"We are very excited about the FDA approval of KORSUVA™ injection," said Abbas Hussain, Chief Executive Officer of Vifor Pharma "There is a significant unmet medical need for a targeted therapy, and we believe that KORSUVA™ injection can fundamentally change the treatment paradigm for adult CKD-aP patients undergoing dialysis. We are committed to bringing this first-in-class medicine to U.S. hemodialysis patients as fast as possible, together with our partner Cara Therapeutics."

"We are pleased to see that KORSUVA™ injection has received FDA approval as the first treatment option approved for moderate to severe pruritus in adult CKD patients on hemodialysis", commented Dr. Frank Maddux, Global Chief Medical Officer of Fresenius Medical Care, "Participating in the robust clinical trial program we have learned that KORSUVA™ injection represents an effective treatment option. We have seen substantial improvement in symptoms and meaningful relief for people suffering from severe and debilitating itch."

This approval is based on the New Drug Application filing that was supported by positive data from two pivotal Phase 3 trials – KALM-1, conducted in the U.S. (New England Journal of Medicine 2020; 382:222-232), and the global KALM-2, as well as supportive data from an additional 32 clinical studies.KORSUVA™ injection was found to be generally well tolerated.

Vifor Pharma and Cara have agreed to an exclusive license to commercialize KORSUVA™ in the United States. That agreement features a Cara 60%, Vifor Pharma 40% profit-sharing arrangement in non-Fresenius Medical Care clinics in the U.S. Under a previous agreement, Vifor Fresenius Medical Care Renal Pharma and Cara Therapeutics have agreed to market KORSUVA™ injection to Fresenius Medical Care North America dialysis clinics in the U.S. under a Cara 50%, Vifor Pharma 50% profit-sharing arrangement.

Vifor Pharma and Cara Therapeutics are in the process of submitting the required documentation to the U.S. Centers for Medicare and Medicaid Services (CMS) to ensure timely reimbursement and patient access to KORSUVA™ injection. Vifor Pharma expects to begin promoting KORSUVA™ Injection in Q1 2022 with reimbursement expected in H1 2022, subject to CMS timelines.

Conference Call

Cara management will host a conference call today at 5:00 p.m. ET to discuss the approval of KORSUVA injection for the treatment of moderate-to-severe pruritus in hemodialysis patients.

To participate in the conference call, please dial (855) 445-2816 (domestic) or (484) 756-4300 (international) and refer to conference ID 1485906. A live webcast of the call can be accessed under "Events & Presentations" in the News & Investors section of the Company's website at www.CaraTherapeutics.com.

An archived webcast recording will be available on the Cara website beginning approximately two hours after the call.

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About Cara Therapeutics

Cara Therapeutics is a clinical-stage biopharmaceutical company focused on developing and commercializing new chemical entities designed to alleviate pruritus by selectively targeting peripheral kappa opioid receptors, or KORs. Cara is developing a novel and proprietary class of product candidates, led by KORSUVA™ (CR845/difelikefalin), a first-in-class KOR agonist that targets the body’s peripheral nervous system, as well as certain immune cells. In two Phase 3 trials, KORSUVA injection has demonstrated statistically significant reductions in itch intensity and concomitant improvement in quality of life measures in hemodialysis patients with moderate-to-severe chronic kidney disease-associated pruritus (CKD-aP). Oral KORSUVA has completed Phase 2 trials for the treatment of pruritus in patients with CKD and atopic dermatitis and is currently in Phase 2 trials in primary biliary cholangitis and notalgia paresthetica patients with moderate-to-severe pruritus.

About Vifor Pharma Group

Vifor Pharma Group is a global pharmaceuticals company. It aims to become the global leader in iron deficiency, nephrology and cardio-renal therapies. The company is a partner of choice for pharmaceuticals and innovative patient-focused solutions. Vifor Pharma Group strives to help patients around the world with severe and chronic diseases lead better, healthier lives. The company develops, manufactures and markets pharmaceutical products for precision patient care. Vifor Pharma Group holds a leading position in all its core business activities and consists of the following companies: Vifor Pharma and Vifor Fresenius Medical Care Renal Pharma (a joint company with Fresenius Medical Care). Vifor Pharma Group is headquartered in Switzerland, and listed on the Swiss Stock Exchange (SIX Swiss Exchange, VIFN, ISIN: CH0364749348).

For more information, please visit viforpharma.com

About KORSUVA™ Injection

KORSUVA is a kappa opioid receptor agonist developed in Cara laboratories and indicated for the treatment of moderate-to-severe pruritus associated with chronic kidney disease (CKD-aP) in adults undergoing hemodialysis (HD). KORSUVA Injection is not a federally controlled substance.

Breakthrough Therapy Designation was received from the FDA for KORSUVA Injection for the treatment of CKD-aP in HD patients and the New Drug Application was evaluated by the FDA with Priority Review.

Important Safety Information

Warnings and Precautions

Dizziness, Somnolence, Mental Status Changes, and Gait Disturbances: These adverse reactions, including falls, have occurred in patients taking KORSUVA and may subside with continued treatment. Concomitant use of centrally acting depressant medications, sedating antihistamines, and opioid analgesics may increase the likelihood of these adverse reactions and should be used with caution during treatment with KORSUVA.

Risk of Driving and Operating Machinery: Dizziness, somnolence, and mental status changes have occurred in patients taking KORSUVA. KORSUVA may impair the mental or physical abilities needed to perform potentially hazardous activities such as driving a car and operating machinery. Advise patients not to drive or operate dangerous machinery until the effect of KORSUVA on their ability to do so is known.

Adverse Reactions

The most common adverse reactions (incidence ≥2% and ≥1% higher than placebo) were diarrhea (9.0%), dizziness (6.8%), nausea (6.6%), gait disturbances, including falls (6.6%), hyperkalemia (4.7%), headache (4.5%), somnolence (4.2%), and mental status changes (3.3%).

Use in Specific Populations

Severe Hepatic Impairment: The influence of severe hepatic impairment on the pharmacokinetics of KORSUVA in subjects undergoing hemodialysis (HD) has not been evaluated; therefore, use of KORSUVA in this population is not recommended.
Geriatric Use: The incidence of somnolence was higher in KORSUVA-treated subjects aged 65 years and older (7.0%) than in KORSUVA-treated subjects less than 65 years of age (2.8%). The incidence was comparable in both placebo age groups (3.0% and 2.1%, respectively).

Indication

KORSUVA is indicated for the treatment of moderate to severe pruritus associated with chronic kidney disease (CKD-aP) in adults undergoing hemodialysis (HD).

Limitation of Use: KORSUVA has not been studied in patients on peritoneal dialysis and is not recommended for use in this population.

Please see KORSUVA™ injection full **Prescribing Information** at **www.korsuva.com.**

About Chronic Kidney Disease-associated Pruritus

CKD-aP is an intractable systemic itch condition that occurs with high frequency and intensity in patients with chronic kidney disease undergoing dialysis. Pruritus has also been reported in patients with stage III-V CKD who are not on dialysis. Aggregate, longitudinal, multi-country studies estimate the weighted prevalence of CKD-aP to be approximately 40% in patients with end-stage renal disease (ESRD), with approximately 25% of patients reporting severe pruritus. The majority of dialysis patients (approximately 60 to 70%) report pruritus, with 30 to 40% reporting moderate or severe pruritus.[1,2,3] Recent data from the ITCH National Registry Study showed that among those with pruritus, approximately 59% experienced symptoms daily or nearly daily for more than a year. Given its association with CKD/ESRD, most afflicted patients will continue to have symptoms for months or years, with currently employed antipruritic treatments, such as antihistamines and corticosteroids, unable to provide consistent, adequate relief. Moderate-to-severe chronic pruritus has repeatedly been shown to directly decrease quality of life, contribute to symptoms that impair quality of life (such as poor sleep quality), and is associated with depression.[4] CKD-aP is also an independent predictor of mortality among hemodialysis patients, mainly related to increased risk of inflammation and infections.

Forward-looking Statements

Statements contained in this press release 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 potential timeline for launch of KORSUVA™ injection, the potential timeline for reimbursement and the potential of KORSUVA™ injection to be a therapeutic option for CKD-aP in dialysis dependent patients. 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's filings with the Securities and Exchange Commission, including the "Risk Factors" section of Cara's Annual Report on Form 10-K for the year ended 31 December 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. Except to the extent required by law, Cara undertakes no obligation to update such statements to reflect events that occur or circumstances that exist after the date on which they were made.

References:

[1] Pisoni RL, et al. Pruritus in haemodialysis patients: international results from the Dialysis Outcomes and Practice Patterns Study. Nephrol Dial Transplant. 2006; 21:3495-3505.

[2] Ramakrishnan K, 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.

[3] Sukul et al. Self-reported Pruritus and Clinical, Dialysis-Related, and Patient-Reported Outcomes in Hemodialysis Patients. Kidney Med. 2020 Nov 21;3(1):42-53.

[4] Mathur VS, et al. A longitudinal study of Uremic Pruritus in hemodialysis patients. Clin J Am Soc Nephrol. 2010; 5(8):1410-1419.