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): December 20, 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 7.01. Regulation FD Disclosure.

On December 20, 2021, Cara Therapeutics, Inc. (the "Company") issued a press release announcing that the U.S. Centers for Medicare & Medicaid Services ("CMS") granted the Company's Transition Drug Add-on Payment Adjustment ("TDAPA") for KORSUVA™ (difelikefalin) injection ("KORSUVA injection") in the anti-pruritic functional category.

A copy of the press release is being furnished to the Securities and Exchange Commission as Exhibit 99.1 to this Form 8-K and is incorporated by reference to this Item 7.01.

The information furnished pursuant to this Item 7.01, including Exhibit 99.1, shall not be deemed to be "filed" for purposes of Section 18 of the Securities Exchange Act of 1934 (the "Exchange Act") or otherwise 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 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.

Item 8.01. Other Events.

On December 20, 2021, the Company announced that CMS has granted TDAPA to KORSUVA injection in the anti-pruritic functional category. TDAPA will apply to KORSUVA beginning April 4, 2022 for two years.

CMS expressed in its written communication to the Cara and Vifor Pharma, a continuing interest in engaging with the companies regarding potential post-TDAPA support to ensure all beneficiaries with end-stage renal disease have access to innovative products such as KORSUVA injection.

Item 9.01. Financial Statements and Exhibits.

(d) Exhibits

Exhibit No.	Description
99.1	Press Release, dated December 20, 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: December 20, 2021

Exhibit 99.1

Cara Therapeutics Announces CMS Grants TDAPA to KORSUVA™ (difelikefalin) Injection

KORSUVA receives TDAPA reimbursement beginning April 2022

U.S. commercial launch on track for early second quarter 2022

Stamford, Conn. Dec. 20, 2021 – Cara Therapeutics, Inc. (Nasdaq: CARA) today announced that the U.S. Centers for Medicare & Medicaid Services (CMS) has granted Transitional Drug Add-On Payment Adjustment (TDAPA) to KORSUVA™ (difelikefalin) injection in the anti-pruritic functional category. TDAPA will apply to KORSUVA injection beginning April 4, 2022, for two years. KORSUVA injection was approved by the U.S. Food and Drug Administration (FDA) in August 2021 for the treatment of moderate-to-severe pruritus associated with chronic kidney disease in adults undergoing hemodialysis.

TDAPA enables payment for new injectable end-stage renal disease (ESRD)-related therapies to be reimbursed outside of the ESRD Prospective Payment System (PPS) bundle.

As KORSUVA injection is just the second product to be approved for TDAPA, CMS expressed in its written communication to Cara and Vifor Pharma, Cara's U.S. commercial partner for KORSUVA injection, a continuing interest in engaging with the companies regarding potential post-TDAPA support to ensure all beneficiaries with ESRD have access to innovative products such as KORSUVA injection.

"Receiving TDAPA from CMS is a crucial step toward the commercial launch of KORSUVA injection, which we believe will benefit thousands of chronic kidney disease patients undergoing dialysis who suffer from pruritus," said Christopher Posner, President and Chief Executive Officer of Cara Therapeutics. "We are pleased to have secured TDAPA reimbursement for KORSUVA injection and are encouraged by the willingness of CMS leadership to engage with Cara and Vifor Pharma regarding potential post-TDAPA support."

"We are pleased to have secured TDAPA reimbursement in the United States for KORSUVA injection effective April 2022, and we look forward to bringing this important treatment option to the people who need it," said Molly Painter, President USA, Vifor Pharma.

About Cara Therapeutics

Cara Therapeutics is an early commercial-stage biopharmaceutical company leading a new treatment paradigm to improve the lives of patients suffering from pruritus. The company's novel KORSUVA™ (difelikefalin) injection is the first and only FDA-approved treatment for moderate-to-severe pruritus associated with chronic kidney disease in adults undergoing hemodialysis. The company is developing an oral KORSUVA (difelikefalin) formulation and plans to initiate Phase 3 programs in the first quarter of 2022 for the treatment of pruritus in patients with atopic dermatitis and non-dialysis-dependent chronic kidney disease, Phase 2 trials of oral KORSUVA are ongoing in primary biliary cholangitis and notalgia paresthetica patients with moderate-to-severe pruritus. For more information, visit www.caratherapeutics.com and follow the company on Twitter, LinkedIn and Instagram.

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 post-TDAPA reimbursement and 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. 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 Quarterly Report on Form 10-Q for the quarter ended September 30, 2021 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.

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