Cara Therapeutics Announces Outcome from Dose-Finding Part A of KIND 1 Study Evaluating Oral Difelikefalin for Moderate-to-Severe Pruritus in Patients with Atopic Dermatitis

December 18, 2023

– Oral difelikefalin as adjunct to topical corticosteroids (TCS) did not demonstrate meaningful clinical benefit compared to TCS alone; As a result, Cara will discontinue its clinical program in pruritus associated with atopic dermatitis –

– Late-stage oral difelikefalin clinical programs for pruritus associated with notalgia paresthetica and advanced chronic kidney disease continue to enroll on track with key data readouts expected in 2H24 –

– Cara expects to end 2023 with approximately $100 million in cash –

STAMFORD, Conn., Dec. 18, 2023 (GLOBE NEWSWIRE) -- Cara Therapeutics, Inc. (Nasdaq: CARA), a commercial-stage biopharmaceutical company leading a new treatment paradigm to improve the lives of patients suffering from pruritus, today announced the outcome from the dose-finding Part A of the KIND 1 study evaluating the efficacy and safety of oral difelikefalin as adjunct therapy to topical corticosteroids (TCS) for moderate-to-severe pruritus in adult patients with atopic dermatitis (AD). Oral difelikefalin as adjunct to TCS did not demonstrate a meaningful clinical benefit compared to TCS alone, resulting in the Company's decision to discontinue its clinical program in pruritus associated with atopic dermatitis.

"We are disappointed with the outcome of this study recognizing that comparing the adjunctive use of oral difelikefalin with TCS to TCS alone represented a high clinical bar based on anticipated real-world commercial use. Importantly, we believe that there is no readthrough to our other late-stage clinical programs for oral difelikefalin as monotherapy without TCS in different indications and patient populations, namely notalgia paresthetica (NP) and advanced chronic kidney disease (CKD)," said Joana Goncalves, MD, Chief Medical Officer of Cara Therapeutics. "On behalf of the Cara team, I would like to thank the patients and investigators who participated in this trial and our team for their unwavering commitment to its execution."

KIND 1 was a Phase 3, two-part, multicenter, randomized, double-blind, controlled study to evaluate the efficacy and safety of oral difelikefalin as adjunct therapy to TCS for moderate-to-severe pruritus in adults with AD. In Part A, patients (n=287) were randomized to receive oral difelikefalin 0.25 mg tablets twice a day (BID) plus TCS, difelikefalin 0.5 mg tablets BID plus TCS, placebo tablets BID plus TCS or placebo tablets BID plus vehicle. The primary endpoint was the proportion of patients with a ≥4-point improvement at Week 12 from baseline in the worst itch NRS.

Oral difelikefalin as adjunct therapy to TCS did not demonstrate a meaningful clinical benefit compared to TCS alone. Oral difelikefalin was generally well tolerated with a safety profile similar to prior trials.

Cara expects to end 2023 with approximately $100 million in cash. This amount includes the $17.5 million already received from HealthCare Royalty, less certain expenses, and the first milestone payment of $20 million, which was triggered by the achievement of the milestone this month and is expected to be received by year-end 2023.

About Cara Therapeutics

Cara Therapeutics is a commercial-stage biopharmaceutical company leading a new treatment paradigm to improve the lives of patients suffering from pruritus. The Company's 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 formulation of difelikefalin and has a Phase 3 program ongoing for the treatment of moderate-to-severe pruritus in patients with advanced chronic kidney disease and a Phase 2/3 program for moderate-to-severe pruritus in patients with notalgia paresthetica. For more information, visit www.CaraTherapeutics.com and follow the company on X (Twitter), LinkedIn and Instagram.

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 Company's plans to discontinue its clinical program in pruritus associated with atopic dermatitis, timing of enrollment and data readouts from the Company's planned and ongoing clinical trials, and the Company's cash balance at year end. Because such statements are subject to risks and uncertainties, actual results may differ materially from those expressed or implied by such forward-looking statements. These risks and uncertainties include the risks inherent in the launch of new products, including that our commercial partners may not perform as expected, risks inherent in the clinical and regulatory development of pharmaceutical products, and the risks 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 ending December 31, 2022 and its other documents subsequently filed with or furnished to the Securities and Exchange Commission, including its Form 10-Q for the quarter ended September 30, 2023. 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, except as required by law.

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