Cara Therapeutics Presents Late-Breaking Results of the KOMFORT Phase 2 Trial of Oral Difelikefalin for Pruritus in Notalgia Paresthetica at the 31st EADV Congress

September 8, 2022

– Study achieved primary endpoint of Worst Itch-Numeric Rating Scale score change from baseline at Week 8 (p=0.001) –

– Significant reduction of itch intensity was evident at Day 1 and effect was maintained through Week 8 –

– Significantly greater proportion of patients who received oral difelikefalin vs. placebo achieved a complete response in WI-NRS at Week 8 –

STAMFORD, Conn., Sept. 08, 2022 (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 results from the KOMFORT Phase 2 clinical trial of oral difelikefalin for the treatment of moderate-to-severe pruritus in notalgia paresthetica (NP). The data will be presented today by Mark Lebwohl, M.D., the lead investigator and Professor and Dean for Clinical Therapeutics and Chairman Emeritus of the Department of Dermatology at the Icahn School of Medicine at Mount Sinai, during a late-breaking news session at the 31st European Academy of Dermatology and Venereology (EADV) Congress.

The presentation includes data from 125 patients with NP and moderate-to-severe pruritus who were randomized to receive oral difelikefalin 2 mg twice daily or placebo over an 8-week treatment period.

The primary efficacy endpoint of change from baseline in the weekly mean of the daily 24-hour Worst Itch-Numeric Rating Scale (WI-NRS) score at Week 8 was achieved (-4.0 difelikefalin vs. -2.4 placebo, p=0.001). A statistically significant reduction in itch intensity was observed with oral difelikefalin at Day 1 compared to placebo and the effect was maintained through Week 8.

Other endpoints included a ≥4-point improvement in WI-NRS, complete response in WI-NRS and safety assessments. A significantly greater proportion of patients achieved a ≥4-point improvement in WI-NRS score at Week 8 with oral difelikefalin vs. placebo (41% difelikefalin vs. 18% placebo, p=0.007). In addition, oral difelikefalin met the complete response endpoint, defined as a WI-NRS score of 0 or 1 for 70% of the daily non-missing WI-NRS scores for the week. At Week 8, a significantly greater proportion of patients receiving oral difelikefalin vs. placebo achieved a complete response (22% difelikefalin vs. 5% placebo, p<0.01).

Oral difelikefalin was generally well tolerated, with all adverse events in difelikefalin-treated patients reported as mild or moderate in severity. Nausea, headache, dizziness, constipation, and increased urine output were more commonly reported in patients on difelikefalin.

Virtual NP Event

Cara Therapeutics will host a virtual event focused on NP on Tuesday, September 20, 2022, from 11:00 a.m. to 12:15 p.m. ET. The presentation will highlight the new data from the KOMFORT Phase 2 clinical trial of oral difelikefalin in NP, as well as feature two key opinion leaders who will discuss the scientific rationale for oral difelikefalin in NP and the significant unmet clinical need. An interactive Q&A session will follow the presentation.

A live audio webcast of the presentation and accompanying slides will be accessible under “Events & Presentations” in the News & Investors section of the Company’s website at www.CaraTherapeutics.com. A replay of the webcast will be archived on the Company’s website following the presentation.

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 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 formulation of difelikefalin and has initiated Phase 3 programs for the treatment of pruritus in patients with non-dialysis dependent advanced chronic kidney disease and atopic dermatitis. The Company has completed a Phase 2 proof-of-concept trial of oral difelikefalin for the treatment of moderate-to-severe pruritus in patients with notalgia paresthetica. A Phase 2 proof-of-concept trial in primary biliary cholangitis patients with moderate-to-severe pruritus is ongoing. For more information, visit www.CaraTherapeutics.com and follow the company on 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 potential for the Company’s product candidates to be alternatives in the therapeutic areas investigated, including NP, and the potential for oral difelikefalin 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 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, 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. 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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