



C4 Therapeutics Receives Study May Proceed Letter from U.S. FDA to Initiate Phase 1/2 Clinical Trial of CFT1946, an Orally Bioavailable BiDAC™ Degradar, in BRAF-V600 Mutant Solid Cancers

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Phase 1/2 Clinical Trial Will Study CFT1946 in BRAF-V600 Mutant Solid Cancers Including Lung, Colorectal and Melanoma; Trial Initiation Expected by Year End 2022

WATERTOWN, Mass., Sept. 29, 2022 (GLOBE NEWSWIRE) -- C4 Therapeutics, Inc. (C4T) (Nasdaq: CCCC), a clinical-stage biopharmaceutical company dedicated to advancing targeted protein degradation science to develop a new generation of small-molecule medicines and transform how disease is treated, today announced it has received a Study May Proceed Letter from the United States Food and Drug Administration (FDA) to begin a Phase 1/2 trial for CFT1946, an orally bioavailable mutant-selective BiDAC™ degrader for the treatment of BRAF-V600 mutant solid tumors.

"The Study May Proceed Letter from the FDA, which marks C4T's third successful oncology investigational new drug application in less than two years, demonstrates the power of our TORPEDO platform to build an exciting portfolio of degrader medicines that have the potential to transform how diseases are treated," said Andrew Hirsch, president and chief executive officer of C4 Therapeutics. "We designed CFT1946 to be a potent and selective degrader of mutant BRAF-V600, which accounts for approximately 50,000 cancer diagnoses annually. We believe our innovative therapeutic candidate may overcome some limitations of BRAF inhibitor treatments to offer cancer patients the potential for deeper and more durable responses."

The Phase 1/2 clinical trial will primarily investigate safety, tolerability, and anti-tumor activity, with secondary and exploratory objectives to characterize the pharmacokinetic and pharmacodynamic profile of CFT1946. The initial arm of the Phase 1 portion of the study will evaluate CFT1946 as a single agent in patients with BRAF-V600 mutant solid tumors. As the Phase 1 trial progresses, an additional arm of the trial will evaluate CFT1946 in combination with trametinib in patients with BRAF-V600 mutant solid tumors. Following the identification of the recommended dose, the Phase 2 portion of the trial is expected to expand to three investigational arms to evaluate: (1) CFT1946 monotherapy in patients with V600 mutant melanoma or non-small cell lung cancer (NSCLC) after prior BRAF inhibitor treatment; (2) CFT1946 in combination with trametinib in patients with V600 mutant melanoma or NSCLC after prior BRAF inhibitor treatment; and (3) CFT1946 in combination with trametinib in patients with V600 mutant NSCLC who have not previously been treated with a BRAF inhibitor.

About C4 Therapeutics

C4 Therapeutics (C4T) (Nasdaq: CCCC) is a clinical-stage biopharmaceutical company dedicated to delivering on the promise of targeted protein degradation science to create a new generation of medicines that transform patients' lives. C4T is leveraging its TORPEDO® platform to efficiently design and optimize small-molecule medicines that harness the body's natural protein recycling system to rapidly degrade disease-causing proteins, offering the potential to overcome drug resistance, drug undruggable targets and improve patient outcomes. C4T is advancing multiple targeted oncology programs to the clinic and expanding its research platform to deliver the next wave of medicines for difficult-to-treat diseases. For more information, please visit www.c4therapeutics.com.

About CFT1946

CFT1946 is an orally bioavailable BiDAC degrader designed to be potent and selective against BRAF-V600 mutant targets. In pre-clinical studies, CFT1946 is active in vivo and in vitro in models with BRAF-V600E-driven disease and in the escape mutant BRAF models. C4T is advancing CFT1946 to the clinic to study treatment for BRAF-V600 mutant solid tumors including lung, colorectal or melanoma.

Forward-Looking Statements

This press release contains "forward-looking statements" of C4 Therapeutics, Inc. within the meaning of the Private Securities Litigation Reform Act of 1995. These forward-looking statements may include, but may not be limited to, express or implied statements regarding our ability to develop potential therapies for patients; the design and potential efficacy of our therapeutic approaches; the predictive capability of our TORPEDO® platform in the development of novel, selective, orally bioavailable degraders; the potential timing, design and advancement of our pre-clinical studies and clinical trials, including the potential timing for regulatory authorization related to clinical trials and other clinical development activities; our ability and the potential to successfully manufacture and supply our product candidates for clinical trials; our ability to replicate results achieved in our pre-clinical studies or clinical trials in any future studies or trials; and regulatory developments in the United States and foreign countries. Any forward-looking statements in this press release are based on management's current expectations and beliefs of future events and are subject to a number of risks and uncertainties that could cause actual results to differ materially and adversely from those set forth in or implied by such forward-looking statements. These risks and uncertainties include, but are not limited to: uncertainties related to the initiation, timing, advancement and conduct of pre-clinical and clinical studies and other development requirements for our product candidates; the risk that any one or more of our product candidates will cost more to develop or may not be successfully developed and commercialized; and the risk that the results of pre-clinical studies and/or clinical trials will or will not be predictive of results in connection with future studies or trials. For a discussion of these and other risks and uncertainties, and other important factors, any of which could cause our actual results to differ from those contained in the forward-looking statements, see the section entitled "Risk Factors" in C4 Therapeutics' most recent Annual Report on Form 10-K and/or Quarterly Report on Form 10-Q, as filed with the Securities and Exchange Commission. All information in this press release is as of the date of the release, and C4 Therapeutics undertakes no duty to update this information unless required by law.

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