C4 Therapeutics Announces FDA Clearance of Investigational New Drug Application for CFT8919, an Orally Bioavailable BiDAC™ Degrader Targeting EGFR L858R for Non-Small Cell Lung Cancer

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WATERTOWN, Mass., July 05, 2023 (GLOBE NEWSWIRE) -- C4 Therapeutics, Inc. (C4T) (Nasdaq: CCCC), a clinical-stage biopharmaceutical company dedicated to advancing targeted protein degradation (TPD) science to develop a new generation of small-molecule medicines and transform how disease is treated, today announced that the U.S. Food and Drug Administration (FDA) has cleared the company's investigational new drug (IND) application for CFT8919, an orally bioavailable BiDAC™ degrader designed to be potent and selective against EGFR L858R for non-small cell lung cancer (NSCLC) patients.

This milestone marks C4T's fourth IND clearance from its proprietary TORPEDO ® platform. In May 2023, C4T and Betta Pharmaceuticals entered into an exclusive licensing agreement for the development and commercialization of CFT8919 in Greater China, including Hong Kong SAR, Macau SAR and Taiwan. In China, approximately 693,000 patients were diagnosed with NSCLC in 2020 and approximately 40% of these cases are driven by the EGFR mutation. The L858R mutation is the second most common EGFR mutation, found in approximately 40% of NSCLC patients with EGFR mutations in China. Betta Pharmaceuticals is responsible for preparing and submitting a Clinical Trial Application to the National Medical Products Administration in China and plans to commence a first-in-human clinical trial of CFT8919 in China. C4T expects to initiate clinical trial activities outside Greater China following the completion of Betta Pharmaceuticals' Phase 1 dose escalation study in Greater China.

About CFT8919
CFT8919 is an orally bioavailable allosteric BiDAC™ degrader that is designed to be potent and selective against EGFR bearing an oncogenic L858R mutation. In preclinical studies, CFT8919 is active in *in vitro* and *in vivo* models of L858R driven non-small cell lung cancer. Importantly, in preclinical studies, CFT8919 retains full activity against additional EGFR mutations that confer resistance against approved EGFR inhibitors including L858R-C797S, L858R-T790M, and L858R-T790M-C797S. In 2023, C4T and Betta Pharmaceuticals entered into an exclusive licensing agreement for the development and commercialization of CFT8919 in Greater China, including Hong Kong SAR, Macau SAR and Taiwan.

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 transforms 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.

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 BiDAC™ and MonoDAC™ degraders; the potential timing, design and advancement of our or our partner's clinical trials, including the potential timing for and receipt of regulatory authorization related to clinical trials and other clinical development activities including clinical trial commencement; our ability and the potential to successfully manufacture and supply our product candidates for clinical trials; our ability to replicate results achieved in our preclinical studies or clinical trials in any future studies or trials; regulatory developments in the United States, Greater China and other foreign countries; our ability to fund our future operations; and our ability to realize the anticipated benefits of our collaboration with Betta Pharmaceuticals. 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 preclinical 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 preclinical 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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