C4 Therapeutics Announces FDA Clearance of Investigational New Drug Application for CFT7455, an Orally Bioavailable MonoDAC for Hematologic Malignancies

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– Phase 1/2 Clinical Study of CFT7455 Expected to Initiate in 1H 2021 –

WATERTOWN, Mass., Jan. 19, 2021 (GLOBE NEWSWIRE) -- C4 Therapeutics, Inc. (C4T) (Nasdaq: CCCC), a biopharmaceutical company pioneering a new class of small-molecule medicines that selectively destroy disease-causing proteins through degradation, today announced that the U.S. Food and Drug Administration (FDA) has cleared the company's investigational new drug (IND) application for its lead product candidate, CFT7455, an orally bioavailable MonoDAC (Monofunctional Degradation Activating Compound) targeting IKZF1/3 for the treatment of hematologic malignancies such as multiple myeloma and non-Hodgkin lymphomas, including peripheral T cell lymphoma and mantle cell lymphoma. The FDA has completed its 30-day safety review and granted approval for the company to proceed with the proposed Phase 1/2 clinical trial for CFT7455.

"The clearance of our first IND is an important milestone for the company, moving us closer to our goal of transforming the treatment of cancer with novel medicines that destroy, rather than inhibit, disease causing proteins," said Andrew Hirsch, president and chief executive officer of C4 Therapeutics. "With FDA clearance achieved, we are on track to advance CFT7455 into the clinic in the first half of 2021 and we look forward to replicating the impressive efficacy we saw pre-clinically in patients with multiple myeloma and non-Hodgkin lymphomas. This is the first of the four programs that we expect to put into the clinic by the end of 2022, each of which was developed through our TORPEDO™ platform."

The Phase 1/2 clinical trial will be an open-label, two-part dose-escalation and expansion study evaluating CFT7455 across multiple hematologic malignancies. The Phase 1 portion of the trial will explore CFT7455 as a single agent in patients with relapsed or refractory (R/R) multiple myeloma (MM) and non-Hodgkin lymphomas (NHL), and in parallel in combination with dexamethasone in R/R MM patients. Following the identification of an optimal dose, the Phase 2 expansion portion of the trial will enroll additional investigational arms including patients with MM, as single agent and in combination with dexamethasone, and as single agent in patients with mantle cell lymphoma and peripheral T-cell lymphoma, two subtypes of NHL. The trial will primarily investigate safety and tolerability, with key secondary objectives to characterize the pharmacokinetic and pharmacodynamic profile and anti-tumor activity of CFT7455.

About C4 Therapeutics
C4 Therapeutics (C4T) is a biopharmaceutical company focused on harnessing the body's natural regulation of protein levels to develop novel therapeutic candidates to target and destroy disease-causing proteins for the treatment of cancer, neurodegenerative conditions and other diseases. This targeted protein degradation approach offers advantages over traditional therapies, including the potential to treat a wider range of diseases, reduce drug resistance, achieve higher potency, and decrease side effects through greater selectivity. To learn more about C4 Therapeutics, 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 degraders; the potential timing, design and advancement of our preclinical studies and clinical trials, including the potential timing for regulatory authorization related to clinical trials; 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; our current resources and cash runway; 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 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 clinical trials will be predictive of future 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 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 C4T undertakes no duty to update this information unless required by law.

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