Cidara Therapeutics Announces the Completion of Dosing the First Cohort of Healthy Volunteers in the Phase 1 Trial of CD388 in Development for Universal Prevention and Treatment of Seasonal and Pandemic Influenza

March 31, 2022

CD388 is a drug-Fc conjugate (DFC) from Cidara's Cloudbreak® platform and is designed to transform the standard of care for seasonal influenza prevention

Trial is advancing to dosing subsequent cohorts

Initial safety and pharmacokinetics data from study expected in the second half of 2022

SAN DIEGO, March 31, 2022 (GLOBE NEWSWIRE) -- Cidara Therapeutics, Inc. (Nasdaq: CDTX), a biotechnology company developing long-acting therapeutics designed to help improve the standard of care for patients facing serious diseases, today announced that the first cohort of healthy volunteers has been dosed in its Phase 1 trial of CD388, a highly potent long-acting antiviral immunotherapy designed to deliver universal prevention of seasonal and pandemic influenza. The study is being conducted under an exclusive worldwide license and collaboration agreement with Janssen Pharmaceuticals, Inc. (Janssen), one of the Janssen Pharmaceutical Companies of Johnson & Johnson, to develop and commercialize Cidara's Cloudbreak drug-Fc conjugates (DFCs) for the prevention and treatment of seasonal and pandemic influenza.

The Phase 1 trial (NCT05285137), which dosed its first healthy volunteer in mid-March, is a randomized, double-blind, dose-escalation study to determine the safety, tolerability and pharmacokinetics of intramuscular and subcutaneous administration of CD388 in healthy subjects. To date, dosing of the first, low-dose cohort has been completed and the next mid-dose cohort is advancing as planned.

"Initiating the first human study of a long-acting DFC is a tremendous milestone for Cidara and our Cloudbreak platform. It is also a testament to our team's firm commitment to transforming universal viral protection for all," said Jeffrey Stein, Ph.D. president and chief executive officer of Cidara. "Based on its compelling profile, CD388 has the potential to address a critical unmet need for universal prevention and the treatment of seasonal and pandemic influenza, especially for those who remain insufficiently protected by current flu vaccines, such as patients with compromised immune systems or patients at high risk for severe complications. We are excited to continue advancing CD388 through the clinic with our collaborator, Janssen."

Cidara's Cloudbreak DFCs, which stably couple a highly potent small molecule or peptide to a proprietary variant of a human antibody fragment (Fc), is a fundamentally novel approach to treat and prevent serious viral infections and cancers. For influenza, the long-acting, CD388 DFC is designed to directly inhibit viral proliferation by targeting a conserved region on the viral surface, potentially conferring universal prevention and treatment of Types A and B influenza with a single seasonal dose.

About Cloudbreak® DFCs
Cidara is developing a new generation of immunotherapeutic antivirals from its Cloudbreak platform that couple potent antivirals to a human antibody fragment (Fc). These highly potent, long-acting, drug-Fc conjugates (DFCs) directly inhibit viral proliferation while simultaneously engaging the immune system. In addition to the clinical-stage CD388 program for seasonal and pandemic influenza, Cidara is advancing DFC programs to target other life-threatening viruses, such as RSV, HIV, and SARS-CoV-2, as well as immuno-oncology targets associated with multiple cancers.

About Influenza
Influenza ("the flu") is a contagious viral infection that can cause mild to severe illness, sometimes resulting in death. It's caused by influenza viruses that infect the nose, throat and lungs, and can put people, such as older people, children, and people with certain health conditions, at higher risk for complications.[1] While today's flu vaccines are credited with significant public health benefits and currently offer the best defense against infection, only about 48% of U.S. adults received a vaccine during the 2019–2020 influenza season.[2] Every year, there are an estimated 1 billion cases of influenza, resulting in 290,000 to 650,000 influenza-related respiratory deaths.[3]

About Cidara Therapeutics
Cidara is developing long-acting therapeutics designed to improve the standard of care for patients facing serious diseases. The Company's portfolio is comprised of new approaches aimed at transforming existing prevention and treatment paradigms, first with its lead Phase 3 antifungal candidate, rezafungin, in addition to drug-Fc conjugates (DFCs) targeting viral and oncology diseases from Cidara's proprietary Cloudbreak platform. Cidara is headquartered in San Diego, California. For more information, please visit www.cidara.com.

Forward-Looking Statements
This release contains "forward-looking statements" within the meaning of Section 27A of the Securities Act of 1933, as amended, and Section 21E of the Securities Exchange Act of 1934, as amended, and such forward-looking statements are made pursuant to the safe harbor provisions of the Private Securities Litigation Reform Act of 1995. "Forward-looking statements" describe future expectations, plans, results, or strategies and are generally preceded by words such as "anticipates," "expect," "may," "plan" or "will". Forward-looking statements in this release include, but are not limited to, statements related to the potential for influenza DFCs, including CD388, to provide universal protection against all influenza strains for an entire season, whether CD388 will be clinically effective in a range of patients including immunocompromised patients, whether Cidara will present preliminary results from a Phase 1 clinical trial for CD388 during the second half of 2022, and whether clinical data ultimately demonstrate that CD388 provides clinical advantages compared to currently approved influenza vaccines and therapeutics. Such statements are subject to a multitude of risks and uncertainties that could cause future circumstances, events, or results to differ materially from those projected in the forward-looking statements, such as unanticipated delays in or negative results from Cidara's preclinical or clinical trials, delays in action by regulatory authorities due to limitations on inspections and other COVID-19-related effects, and impacts of the COVID-19 pandemic or other obstacles on the enrollment of patients or other aspects of CD388 development. These and other risks are identified under the caption "Risk Factors" in Cidara's most recent Quarterly Report on

Form 10-Q and other filings subsequently made with 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 and are based on management's assumptions and estimates as of such date. Cidara does not undertake any obligation to publicly update any forward-looking statements, whether as a result of the receipt of new information, the occurrence of future events or otherwise.

INVESTOR CONTACT:
Brian Ritchie
LifeSci Advisors
(212) 915-2578
britchie@lifesciadvisors.com

MEDIA CONTACT:
Patrick Bursey
LifeSci Communications
(203) 430-9545
pbursey@lifescicomms.com

1. About Flu. Centers for Disease Control and Prevention. Available at: https://www.cdc.gov/flu/about/index.html. Last accessed January 2022.
2. Flu Vaccination Coverage, United States, 2019–20 Influenza Season. Centers for Disease Control and Prevention. Available at: https://www.cdc.gov/flu/fluvaxview/coverage-1920estimates.htm. Last accessed January 2022.
3. WHO launches new global influenza strategy. World Health Organization. Available at: https://www.who.int/news/item/11-03-2019-who-launches-new-global-influenza-strategy. Last accessed January 2022.