Cidara Therapeutics Announces FDA Acceptance of its Investigational New Drug Application for CD388 for Universal Prevention and Treatment of Influenza

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Cidara intends to initiate the Phase 1 trial in Q1 2022

Drug-Fc conjugate (DFC) CD388 leverages Cidara's Cloudbreak® platform and has the potential to offer significant advantages over current flu vaccines in a single seasonal dose

SAN DIEGO, Feb. 14, 2022 (GLOBE NEWSWIRE) -- Cidara Therapeutics, Inc. (Nasdaq: CDTX), a biotechnology company developing long-acting therapeutics designed to improve the standard of care for patients facing serious diseases, today announced that the U.S. Food and Drug Administration (FDA) has accepted the Company's Investigational New Drug (IND) application for its lead flu drug-Fc conjugate (DFC), CD388 – a highly potent, long-acting antiviral immunotherapy designed to deliver universal prevention and treatment of seasonal and pandemic influenza. Cidara intends to initiate a Phase 1 study in healthy volunteers before the end of the current quarter.

In April 2021, Cidara announced 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 DFCs for the prevention and treatment of seasonal and pandemic influenza. Under the collaboration, Cidara is responsible for the development and manufacturing of CD388 into the clinic and through Phase 2a clinical development, and Janssen is responsible for late-stage development, manufacturing, registration and global commercialization. Janssen will fund the Phase 1 trial-related development costs and all future research, development, manufacturing and commercialization for CD388.

"Receiving this clearance to advance CD388 into the clinic represents an important milestone for Cidara and our Cloudbreak platform. This marks the first opportunity to explore the clinical safety and pharmacokinetics of one of our novel long-acting DFCs," said Jeffrey Stein, Ph.D. president and chief executive officer of Cidara. "There is a significant unmet need for true universal prevention and treatment of seasonal and pandemic influenza, especially for those who are immunocompromised or at high risk for severe complications. We look forward to advancing CD388 and our Cloudbreak influenza program through the clinic with our collaborator, Janssen. Later this year, we expect the availability of new preclinical data for our other antiviral DFCs, including RSV and SARS, as well as preclinical data for our oncology DFCs directed against solid tumors."

Cidara's Cloudbreak platform is a fundamentally new approach to treat and prevent serious viral infections and solid tumors. Cloudbreak DFCs stably couple a highly potent small molecule or peptide to a proprietary variant of a human antibody fragment (Fc). These long-acting, bispecific DFCs are designed to directly inhibit viral proliferation. In influenza, the CD388 targeting domain is an antiviral that binds to a conserved target on the influenza virus's surface, conferring universal antiviral activity, thereby suggesting its use in prevention and treatment.

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. DFCs being studied for the prevention and treatment of seasonal and pandemic influenza have the potential to deliver universal protection for an entire flu season. Cidara is also advancing preclinical and discovery DFC programs to target other life-threatening viruses, such as RSV, HIV, and SARS-CoV-2 strains causing COVID-19, as well as oncology diseases.

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 initiate a Phase 1 clinical trial for CD388 during the first quarter 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 pre-clinical 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.

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