October 2, 2019

ContraFect Announces Plan for a Single Phase 3 Superiority Design Study of Exebacase Following Successful End-of-Phase 2 Meeting with FDA

Primary Endpoint of Clinical Response at Day 14 in Patients withMethicillin-Resistant Staph aureus (MRSA) Bacteremia, including Right-Sided Endocarditis

Study Initiation Planned by Year-End 2019

Conference Call Today at 8:30 a.m. ET to Discuss Phase 3 Plans

YONKERS, N.Y., Oct. 02, 2019 (GLOBE NEWSWIRE) -- ContraFect Corporation (Nasdaq:CFRX), a clinical-stage biotechnology company focused on the discovery and development of direct lytic agents (DLAs), including lysins and amurin peptides, as new medical modalities for the treatment of life-threatening, antibiotic-resistant infections, today announced its plan to initiate a single Phase 3 clinical trial of exebacase for the treatment of patients with *Staphylococcus aureus* bacteremia, including right-sided endocarditis, following its End-of-Phase 2 meeting with the U.S. Food and Drug Administration (FDA). ContraFect has obtained concurrence with the FDA on key design features of the Phase 3 protocol, including the Day 14 primary efficacy endpoint for MRSA bacteremia, including right-sided endocarditis, and that positive results from this single Phase 3 study could support a Biologics License Application (BLA) for approval of exebacase.

“We are very pleased to have obtained clear and readily actionable FDA guidance to proceed with a single Phase 3 study to support the U.S. registration of exebacase,” said Roger J. Pomerantz, MD, President, Chief Executive Officer, and Chairman of ContraFect. “Due to the dramatic increase in antibiotic-resistant strains of bacteria, our healthcare system urgently requires novel anti-infective agents, especially those with highly differentiated mechanisms of action and clinical profiles. Exebacase is the first product candidate of its class and represents the potential of direct lytic agents as an entirely new treatment modality. Exebacase could be the first agent ever to demonstrate superior efficacy compared to traditional antibiotics in treating patients with complicated MRSA bacteremia in a Phase 3 study. We appreciate the efforts of the FDA in working with us to advance exebacase as a streamlined development program.”

“We are excited to be moving at full speed into the exebacase Phase 3 study, with the goal of bringing this potential new medicine to patients who need it as rapidly but as safely as possible. The 43% higher responder rate at Day 14 demonstrated among exebacase-treated MRSA bacteremia patients, compared to those who received antibiotics alone, in our Phase 2 study gives us confidence in exebacase’s ability to improve the clinical cure rates for *Staph aureus* bacteremia and endocarditis. This is particularly true for the most difficult-to-treat patients with complicated MRSA bacteremia, which continues to be a major health concern the world over,” said Cara Cassino, MD, Chief Medical Officer and Executive Vice President of Research and Development at ContraFect.

The Phase 3 DISRUPT trial of exebacase will be a single, randomized, double-blind, placebo-controlled clinical study conducted in the U.S. to assess the efficacy and safety of exebacase in approximately 350 patients with *Staph aureus* bacteremia, including right-sided endocarditis. Patients entering the Phase 3 study will be randomized 2:1 to either exebacase or placebo, with all patients receiving standard-of-care antibiotics. The primary efficacy endpoint will be clinical response at Day 14 in patients with MRSA bacteremia, including right-sided endocarditis. Secondary endpoints will include clinical response at Day 14 in the AII *Staph aureus* bacteremia patient group (MRSA and methicillin-sensitive *Staph aureus* (MSSA)), 30-day all-cause mortality in MRSA patients, and clinical response at later timepoints. The company anticipates initiating the Phase 3 study by the end of 2019, and plans to conduct an interim futility analysis following the enrollment of approximately 60% of the study population.

Conference Call

The Company will host a conference call today, October 2, 2019, at 8:30 a.m. ET to discuss its plans for the development of exebacase for the treatment of patients with *Staph aureus* bacteremia, including endocarditis, following its End-of-Phase 2 meeting with the FDA. To access the call, please dial 866-691-5817 (domestic) or 409-216-0839 (international) and provide Conference ID 5266033. A live webcast of the presentation will be available on the Investors & Media section of the Company’s website at www.contrafect.com. The presentation will also be available as an archived webcast for a limited time.

About ContraFect:

ContraFect is a biotechnology company focused on discovering and developing differentiated biologic therapies for life-threatening, drug-resistant infectious diseases, particularly those treated in hospital settings. An estimated 700,000 deaths worldwide each year are attributed to antimicrobial-resistant infections. We intend to address life threatening infections using our therapeutic product candidates from our platform of DLAs, which include lysins and amurin peptides. Lysins are a new class of DLAs which are recombinantly produced antimicrobial proteins with a novel mechanism of action associated with the rapid killing of target bacteria, eradication of biofilms and synergy with conventional antibiotics. Amurin peptides are a new class of DLAs, which exhibit broad-spectrum activity against a wide range of antibiotic-resistant Gram-negative pathogens, including *Pseudomonas aeruginosa* (*P. aeruginosa*), *Acinetobacter baumannii*, and *Enterobacter* species. We believe that the properties of our lysins and amurin peptides will make them suitable for targeting antibiotic-resistant organisms, such as methicillin-resistant *Staph aureus* (MRSA) and *P. aeruginosa*, which can cause serious infections such as bacteremia, pneumonia and osteomyelitis. We have completed a Phase 2 clinical trial for the treatment of *Staph aureus*

bacteremia, including endocarditis, with our lead lysin candidate, exebacase, which is the first lysin to enter clinical studies in the U.S.

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About Exebacase (CF-301):

Exebacase is a recombinantly-produced lysin (cell wall hydrolase enzyme) with potent bactericidal activity against *Staph aureus*, a major cause of blood stream infections (BSIs) also known as bacteremia. It has a novel, rapid, and specific mechanism of bactericidal action against *Staph aureus*. By targeting a conserved region of the cell wall that is vital to bacteria, resistance is less likely to develop to exebacase. We have completed a Phase 2 superiority design clinical study with exebacase which evaluated its safety, tolerability, efficacy and PK when used in addition to standard-of-care (SOC) antibiotics for the treatment of *Staph aureus* bacteremia, including endocarditis, in adult patients. In a pre-specified analysis of MRSA-infected patients, the clinical responder rate at day 14 in patients treated with exebacase was 43% higher than the clinical responder rate in patients treated with SOC antibiotics alone (74% for patients treated with exebacase compared to 31% for patients treated with SOC antibiotics alone ($p=0.010$)). Additionally, among United States MRSA patients discharged alive from the hospital, the median length of stay was reduced by four days and the 30-day all cause readmission rate was reduced to 16% from 31% in patients treated with exebacase. We believe exebacase has the potential to be a first-in-class treatment for *Staph aureus* bacteremia. Exebacase was licensed from The Rockefeller University and is being developed at ContraFect.

Forward-Looking Statements:

This press release contains, and our officers and representatives may make from time to time, "forward-looking statements" within the meaning of the U.S. federal securities laws. Forward-looking statements can be identified by words such as "projects," "may," "will," "could," "would," "should," "believes," "expects," "anticipates," "estimates," "intends," "plans," "potential," "promise" or similar references to future periods. Examples of forward-looking statements in this release include, without limitation, statements regarding ContraFect's End-of-Phase 2 Meeting with the FDA, Phase 3 plans, designs, results and timing, statements made by ContraFect's chief executive officer and chief medical officer, ContraFect's ability to discover and develop DLAs as new medical modalities for the treatment of life-threatening, antibiotic-resistant infections, the planned call and webcast, ContraFect's ability to address life threatening infections using its therapeutic product candidates from its DLA platform, whether lysins are a new class of DLAs which are recombinantly produced, antimicrobial proteins with a novel mechanism of action associated with the rapid killing of target bacteria, eradication of biofilms and synergy with conventional antibiotics, whether amurins exhibit broad-spectrum activity against a wide range of antibiotic-resistant Gram-negative pathogens, whether the properties of ContraFect's lysins and amurins will make them suitable for targeting antibiotic-resistant organisms, such as *Staph aureus* and *P. aeruginosa*, the potential for exebacase to be a first-in-class treatment for*Staph aureus* bacteremia, statements made regarding exebacase and Phase 2 study results. Forward-looking statements are statements that are not historical facts, nor assurances of future performance. Instead, they are based on ContraFect's current beliefs, expectations and assumptions regarding the future of its business, future plans, strategies, projections, anticipated events and trends, the economy and other future conditions. Because forward-

looking statements relate to the future, they are subject to inherent risks, uncertainties and changes in circumstances that are difficult to predict and many of which are beyond ContraFect's control, including those detailed under the caption "Risk Factors" in ContraFect's filings with the Securities and Exchange Commission. Actual results may differ from those set forth in the forward-looking statements. Important factors that could cause actual results to differ include, among others, our ability to develop treatments for drug-resistant infectious diseases. Any forward-looking statement made by ContraFect in this press release is based only on information currently available and speaks only as of the date on which it is made. Except as required by applicable law, ContraFect expressly disclaims any obligations to publicly update any forward-looking statements, whether written or oral, that may be made from time to time, whether as a result of new information, future developments or otherwise.

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