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ContraFect Completes Enrollment in Phase 2 Clinical Trial Evaluating CF-301 (exebacase) in Patients with Staphylococcus Aureus Bacteremia

Company remains on track to announce top-line results in Q4 2018

YONKERS, N.Y., Sept. 06, 2018 (GLOBE NEWSWIRE) -- [ContraFect Corporation \(Nasdaq:CFRX\)](#), a clinical-stage biotechnology company focused on the discovery and development of protein and antibody therapeutics for life-threatening, drug-resistant infectious diseases, today announced that it has completed enrollment in the Phase 2 clinical trial evaluating its first-in-class lysin, CF-301, as a potential treatment for *Staphylococcus aureus* (*Staph aureus*) bacteremia including endocarditis.

"We are very pleased to have completed enrollment of this Phase 2 superiority study, which is a major milestone in the development of exebacase (CF-301) as a potential new treatment option for patients with *Staph aureus* bacteremia including endocarditis. We thank the investigators, study sites and patients for their ongoing participation," said Cara Cassino, M.D., Chief Medical Officer and Executive Vice President of Research and Development at ContraFect. "*Staph aureus* bacteremia and endocarditis continue to be associated with substantial morbidity and mortality despite conventional antibiotics. We look forward to the topline results of the Phase 2 study later this year, which will inform us of the potential for CF-301 to improve clinical outcomes for these serious, potentially life threatening *Staph aureus* infections."

The multi-center, multi-national, randomized, double-blind, placebo-controlled Phase 2 superiority study is intended to evaluate the potential for CF-301, used in addition to standard-of-care (SOC) antibiotics, to improve clinical cure rates compared to SOC antibiotics alone. The study is ongoing at investigational sites in the United States, Europe, Latin America, Russia and Israel. Approximately 115 patients were planned to be randomized 3:2 to receive either a single dose of CF-301 or placebo administered via intravenous infusion in addition to SOC anti-staphylococcal antibiotics. The primary objectives of the study are to evaluate the safety, tolerability, pharmacokinetics, and efficacy of CF-301.

More information about the study is available at www.clinicaltrials.gov.

About *Staphylococcus aureus* bacteremia:

In the U.S. alone, there are approximately 200,000 hospitalizations for *Staph aureus* bacteremia annually. Mortality rates from this bloodstream infection have been reported as ranging from 20-40% despite conventional antibiotics. *Staph aureus* bacteremia may lead to infectious endocarditis, a serious infection affecting the heart valves. The incidence of infective endocarditis in the U.S. has increased over the past decade and is likely due to the growth of the at-risk populations, such as older, diabetic and hemodialysis patients. *Staph aureus* endocarditis remains difficult to treat with current standard of care antibiotics. One reason for this is biofilm formation which prevents antibiotics from eradicating the bacteria, leading to the need for long courses of antibiotic therapy, which are often unsuccessful and necessitate surgery to eradicate bacteria from infected heart valves. Emerging resistance to conventional antibiotics such as vancomycin and daptomycin represents an additional serious threat which may have serious consequences in terms of increasing morbidity, mortality and health care utilization.

About exebacase (CF-301):

Exebacase (CF-301) is a recombinant bacteriophage-derived lysin with potent bactericidal activity against *Staph aureus*, a major cause of blood stream infections, or bacteremia. CF-301 has the potential to be a first-in-class treatment for *Staph aureus* bacteremia. It has a novel, rapid, and specific mechanism of bactericidal action against *Staph aureus* and does not impact the body's natural bacterial flora. By targeting a conserved region of the cell wall that is vital to bacteria, resistance is less likely to develop to CF-301. Combinations of CF-301 with standard of care antibiotics significantly increased bacterial killing and survival in animal models of disease when compared to treatment with antibiotics or CF-301 alone. In addition, in vitro and in vivo experiments have shown that CF-301 is highly active against biofilm infections. CF-301 was licensed from The Rockefeller University and is being developed at ContraFect. It is the first lysin to enter clinical studies in the U.S.

About ContraFect:

ContraFect is a biotechnology company focused on discovering and developing therapeutic protein and antibody products 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 lysin and monoclonal antibody platforms to target conserved regions of either bacteria or viruses (regions that are not prone to mutation). ContraFect's initial product candidates include new agents to treat antibiotic-resistant infections such as MRSA (Methicillin-Resistant *Staphylococcus aureus*) and influenza. ContraFect's lead product candidate, exebacase (CF-301), is currently in a Phase 2 clinical trial for the treatment of *Staphylococcus aureus* (*Staph aureus*) bacteremia, including endocarditis and is the first lysin to enter clinical studies in the U.S. ContraFect is also conducting research focused on the discovery of lysins to target Gram-negative bacteria.

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 our ability to discover and develop protein and antibody therapeutics for life-threatening, drug-resistant infectious diseases, the potential for CF-301 to be a treatment for *Staph aureus* bacteremia including endocarditis, whether completion of enrollment constitutes a major milestone in the development of exebacase, the timing of the announcement of topline results and whether they will inform us of the potential for CF-301 to improve clinical outcomes for *Staph aureus* infections, whether the Phase 2 trial will evaluate the potential for CF-301 used in addition to SOC antibiotics to improve clinical cure rates compared to SOC antibiotics alone, our ability to address life threatening infections using our therapeutic product candidates from our lysin and monoclonal antibody platforms to target conserved regions of either bacteria or viruses, whether our initial product candidates can treat antibiotic-resistant infections such as MRSA and influenza, our ability to discover new lysins targeting Gram-negative bacteria, statements regarding primary study objectives, enrollment, randomization, *Staph aureus* bacteremia and in vitro and in vivo experiments. 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 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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