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ContraFect Announces Initiation of Phase 2 Study Evaluating CF-301 in Patients with *Staphylococcus aureus* Bacteremia

YONKERS, NY -- (Marketwired) -- 05/25/17 -- [ContraFect Corporation](#) (NASDAQ: CFRX), a biotechnology company focused on the discovery and development of protein and antibody therapeutics for life-threatening, drug-resistant infectious diseases, today announced the initiation of an international Phase 2 study evaluating its first-in-class lysin, CF-301, as a potential treatment of *Staphylococcus aureus* (*Staph aureus*) bacteremia including right sided endocarditis. *Staph aureus* bacteremia and endocarditis are serious life threatening infections, associated with substantial morbidity and mortality despite currently available conventional antibiotics. This multicenter, randomized, double-blind, placebo-controlled study is designed to evaluate the potential for CF-301 to be used in addition to standard-of-care (SOC) antibiotics to significantly improve clinical success rates compared to SOC antibiotics alone. Safety, tolerability, and pharmacokinetics of CF-301 will also be evaluated in the study. The company expects to announce top line results in Q4 2018.

"We are very pleased to initiate the first clinical study of CF-301 in patients with *S. aureus* bacteremia. Based on the extensive amount of pre-clinical data generated, CF-301 has the potential to improve clinical outcomes for these patients by rapid bacterial killing, synergy with conventional antibiotics and clearance of biofilms that complicate *Staph aureus* infections," said Cara Cassino, M.D., EVP of Research and Development and Chief Medical Officer at ContraFect.

"We are excited about the initiation of this trial, and the promise that CF-301, and potentially other lysins in our pipeline, may offer important new advances in the treatment of bacterial infections which are a global health care threat," said Steven C. Gilman, Ph.D., Chairman of ContraFect.

In the United States alone, there are approximately 120,000 cases annually of the bloodstream infection *Staph aureus* bacteremia, which causes approximately 30,000 deaths. *Staph aureus* bacteremia can be further complicated when the infection spreads into the heart muscle, heart valves or lining of the heart, causing endocarditis. Even with current SOC antibiotic therapy, the resulting damage to the heart muscle or heart valves could require surgery for definitive treatment to prevent stroke, heart failure or multi-organ system damage. Of further concern, drug-resistant strains of *Staph aureus* are now evolving additional resistance against SOC antibiotics, which may ultimately result in an increase in

the number of cases and in mortality from *Staph aureus* bacteremia, including endocarditis.

About the Trial:

ContraFect plans to conduct the trial in approximately 70 sites worldwide including North America, South America, and Europe. A total of 115 patients are expected to be enrolled, randomized 3:2 to receive either a single dose of 0.25 mg/kg CF-301 administered via a 2 hour IV infusion in addition to SOC antibiotics or placebo plus SOC antibiotics.

The primary endpoint of the trial is early clinical response. In addition, safety, tolerability, pharmacokinetics, and a number of exploratory clinical and health resource utilization endpoints will be evaluated.

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

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.

About CF-301:

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 *Staphylococcus aureus* (*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.

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, including whether CF-301 has the potential to be a first-in-class lysin therapeutic for the treatment of *Staph aureus* bacteremia including right sided endocarditis, whether CF-301 used in addition to SOC antibiotics can significantly improve clinical success rates compared to SOC antibiotics alone, whether CF-301 can improve clinical outcomes for patients by rapid bacterial killing, synergy with conventional antibiotics and clearance of biofilms which complicate *Staph aureus* infections, whether CF-301 and other lysins in our pipeline will offer important new advances in the treatment of bacterial infections which are a global health care threat, our plans to conduct the trial in approximately 70 sites worldwide including North America, South America, and Europe, our ability to enroll a total of 115 patients, whether we achieve our clinical endpoints, the announcement of top line results in Q4 2018 and 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. 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. 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 and those detailed under the caption "Risk Factors" in ContraFect's Quarterly Report on Form 10-Q for the quarter ended March 31, 2017 and its other filings with the Securities and Exchange Commission. 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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