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ContraFect Announces ANSM Approval of Clinical Trial Application for Exebacase in Prosthetic Joint Infections

YONKERS, N.Y., Nov. 28, 2022 (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, announces today that ANSM, the French National Agency for the Safety of Medicines and Health Products, has authorized its Clinical Trial Application (CTA) for the study of intra-articularly administered exebacase, in the setting of a minimally-invasive arthroscopic debridement, antibiotics, irrigation, and retention (DAIR) procedure in patients with chronic prosthetic joint infection (PJI) of the knee due to *Staphylococcus aureus (S. aureus*) or Coagulase-Negative Staphylococci (CoNS).

“This is a significant milestone for our company as it represents the next opportunity for exebacase to recapitulate the positive and durable results we have observed clinically in the compassionate use setting, after dosing 16 patients. Exebacase presents the potential for a truly revolutionary change to the current treatment paradigm for patients with prosthetic joint infections, which consists of the chronic use of ineffective antibiotic agents leading to expensive and debilitating surgery, whereby the joint is removed and reimplanted 6 to 8 weeks after the patient’s confinement to a hospital bed,” said Roger J. Pomerantz, MD, President, Chief Executive Officer, and Chairman of ContraFect. “PJIs are a completely underserved area of medicine, where no randomized clinical trials have been completed. As the population of the developed world ages, we must find a safe, effective and minimally-invasive way to treat these infections or millions of patients will continue to suffer. Based on promising activity we have seen with exebacase *in vitro*, *in vivo*, and in compassionate uses to date, we look forward to completing what could be the first successful blinded and randomized trial in the field of PJIs.”

The Phase 1b/2 study of exebacase is a randomized, double-blind, placebo-controlled two-part clinical study to be conducted in France to assess the efficacy and safety of exebacase in the setting of an arthroscopic DAIR procedure in patients with chronic PJI of the knee due to *S. aureus* and/or CoNS. Part 1 will evaluate the safety, PK, clinical outcomes, and microbiologic response in patients through Day 42. Up to 2 dose levels of intra-articularly administered exebacase in addition to systemic antibiotics will be studied in up to 2 patient cohorts. Part 2 will consist of a long-term follow-up study of safety and efficacy parameters

in patients who complete Part 1 of the study. Follow-up assessments will be performed on Days 90, 180, 360 and 720.

About ContraFect

ContraFect is a biotechnology company focused on the discovery and development of DLAs, including lysins and amurin peptides, as new medical modalities for the treatment of life-threatening, antibiotic-resistant infections. 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 novel class of DLAs which exhibit broad-spectrum activity against a wide range of antibiotic-resistant Gram-negative pathogens, including *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 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. Exebacase was granted Breakthrough Therapy designation by the FDA for the treatment of MRSA bloodstream infections, including right-sided endocarditis, when used in addition to SOC anti-staphylococcal antibiotics.

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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 ANSM approval, the CTA and the clinical trial, statements made by Dr. Pomerantz, the conduct of the Phase 1b/2 study, ContraFect’s ability to discover and develop DLAs as new medical modalities for the treatment of life-threatening, antibiotic-resistant infections, whether ContraFect will address life-threatening infections using therapeutic 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 are a novel class of DLAs which exhibit broad-spectrum activity against a wide range of antibiotic-resistant Gram-negative pathogens, and whether the properties of ContraFect’s lysins and amurins will make them suitable for targeting antibiotic-resistant organisms, such as MRSA and *P. aeruginosa*. 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, without limitation, that ContraFect has and expects to continue to incur significant losses, ContraFect's need for additional funding, which may not be available, the occurrence of any adverse events related to the discovery, development and commercialization of ContraFect's product candidates such as unfavorable clinical trial results, insufficient supplies of drug products, the lack of regulatory approval, or the unsuccessful attainment or maintenance of patent protection, changes in management may negatively affect ContraFect's business and other important risks detailed under the caption "Risk Factors" in ContraFect's Quarterly Report on Form 10-Q for the quarter ended September 30, 2022 and its other filings with the Securities and Exchange Commission. Actual results may differ from those set forth in the forward-looking statements. 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.

Investor Relations Contacts:

Michael Messinger
ContraFect Corporation
Tel: 914-207-2300
Email: mmessinger@contrafect.com

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