March 18, 2020

ContraFect Reports Fourth Quarter and Full Year 2019 Financial Results and Provides Business Update

YONKERS, N.Y., March 18, 2020 (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 financial results for the fourth quarter and full year ended December 31, 2019.

“We had a remarkable year of ‘firsts’ in 2019, from announcing the first superiority dataset since vancomycin in patients with MRSA bacteremia, to hosting our first R&D day in New York City, to completing our first End-of-Phase 2 meeting with the FDA which led to the initiation of our first Phase 3 trial: the pivotal DISRUPT superiority study, to advancing our first DLA candidate targeting a gram-negative pathogen, CF-370 for *Pseudomonas aeruginosa* infections, towards an IND” said Roger J. Pomerantz, MD, President, Chief Executive Officer, and Chairman of ContraFect. “We continue to demonstrate our commitment to the development of new treatment modalities with the potential for superior clinical outcomes, as recently recognized by the Breakthrough Therapy designation for exebacase for the treatment of MRSA bloodstream infections. These new modalities, now more than ever, must be prioritized as new infectious disease outbreaks take hold and others continue to develop resistance to conventional antibiotics,” he continued.

2019 Highlights

Initiated the Phase 3 DISRUPT Trial of Exebacase

- In December 2019, the Company announced the initiation of the Phase 3 DISRUPT (Direct Lysis of *Staph aureus* Resistant Pathogen Trial) superiority design study of exebacase in patients with *Staph aureus* bacteremia, including right-sided endocarditis and subsequently announced in January 2020 that it began actively dosing patients.

  The Phase 3 DISRUPT study of exebacase is a 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 complicated *Staph aureus* bacteremia, including right-sided endocarditis. Patients enrolled in the Phase 3 study will be randomized 2:1 to receive 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 All *Staph aureus* patients (MRSA and methicillin-sensitive *Staph aureus* (MSSA)), 30-day all-cause mortality in MRSA patients, and clinical response at later timepoints. The company plans to conduct an interim futility analysis following the enrollment of approximately 60% of the study population.

- In September 2019, the Company completed a successful End-of-Phase 2 meeting with the U.S. Food and Drug Administration (FDA). ContraFect obtained concurrence with the FDA on key design features of the Phase 3 protocol, including the study population, efficacy endpoints and safety follow-up parameters. Importantly, the advancement of exebacase under the FDA’s guidance for “streamlined development” provides that with positive results, a single Phase 3 study, together with the full package of Phase 1 and Phase 2 clinical data, along with a robust non-clinical and PK/PD data package, would be sufficient to potentially support a Biologics License Application (BLA) for approval of exebacase.

- In May 2019, the Company hosted its first investor and analyst R&D day that highlighted new data from the exebacase Phase 2 clinical trial, demonstrating that patients with MRSA, who were treated with exebacase and alive at the time of discharge, had a four day lower mean length of hospital stay and meaningful reductions in hospital readmission rates, for both all-cause and *Staph aureus* infection readmissions, compared to patients treated with standard-of-care alone.

- In April 2019, Vance G. Fowler, MD, Professor of Medicine in the Division of Infectious Diseases at Duke University and the principal investigator for the Phase 2 study of exebacase, presented new data from the trial at the 29th European Congress of Clinical Microbiology and Infectious Diseases (ECCMID). The oral presentation was entitled "Exebacase (Lysin CF-301) Improved Clinical Responder Rates In MRSA Bacteremia Including Endocarditis Compared To Standard Of Care Antibiotics Alone In A First-in-Patient Phase 2 Study."

- In January 2019, the Company reported topline data from its Phase 2 clinical trial of exebacase for the treatment of *Staph aureus* bacteremia, including endocarditis, demonstrating clinically meaningful increases in clinical responder rates in the pre-specified MRSA subgroup treated with exebacase, compared to MRSA patients treated with standard-of-care antibiotics alone, at all timepoints tested, including a 43-percentage point higher clinical responder rate at the Day 14 primary efficacy timepoint (p=0.010). Based on final data from this Phase 2 superiority trial, the FDA has granted Breakthrough Therapy designation to exebacase for the treatment of MRSA bloodstream infections (bacteremia), including right-sided endocarditis, when used in addition to standard-of-care (SOC) anti-staphylococcal antibiotics in adult patients.

Advanced Portfolio of Lysins and Amurins Targeting Gram-negative Pathogens

- In December 2019, the Company announced the nomination towards its second IND of its DLA candidate CF-370, targeting *Pseudomonas aeruginosa* (*P. aeruginosa*) based on its potent *in vitro* bactericidal and antibiofilm activity and *in vivo* activity and tolerability in preclinical models. In preclinical rabbit models, single doses of CF-370 alone and in addition to the antibiotic, meropenem, were tested against multi-drug resistant *P. aeruginosa* to evaluate survival and bacterial burden in lung and secondary organs. Strong efficacy signals were observed for a single dose of CF-370 as a monotherapy, showing longer survival compared to vehicle control and reductions in bacterial burden in lung, kidney and spleen as well as synergy with meropenem.

- In September 2019, the Company presented data from an *ex vivo* study of its amurin peptide candidate, Aap2-M1, at the jointly sponsored American Society of Microbiology and European Society of Clinical Microbiology and Infectious Disease (ASM/ESCMID) Conference on Drug Development to Meet the Challenge of Antimicrobial Resistance. Data demonstrated a clinically relevant concentration of Aap2-M1 eradicated *Stenotrophomonas maltophilia* biofilm formed inside hemodialysis catheters removed from patients with suspected catheter-related bloodstream infections in the clinical care setting. These new data provided the first evidence of the activity of an amurin peptide against biofilm formed by a deadly gram-negative pathogen in the setting of human infection.

- The Company also presented an overview of its early research pipeline directed at gram-negative pathogens at the 29th European Congress of Clinical Microbiology and Infectious Diseases (ECCMID) held in April 2019. The "Pipeline Talk" included new data on the ability of lysins targeting gram negative pathogens to re-sensitize carbapenem-resistant *P. aeruginosa* to imipenem.

Announced Multiple Publications

- In November 2019, the peer-reviewed journal, Diagnostic Microbiology and Infectious Disease, published an article titled "In vitro activity of Exebacase (CF-301) against clinical *Staphylococcus aureus* surveillance isolates from the United States, Europe, and Latin America, 2015–2017." The Company's investigation demonstrated the potent *in vitro* activity of exebacase against all MSSA and MRSA surveillance isolates collected between 2015 and 2017 from the US, EU and South America. The MSSA and MRSA groups were equivalently susceptible to exebacase, with $MIC_{50/90}$ values of 0.5/1 mg/L and/or a range of 0.25–1 mg/L.

- In October 2019, the peer-reviewed Antimicrobial Agents and Chemotherapy Journal of the American Society of Microbiology (AAC) published the manuscript titled "Antimicrobial Activity of Exebacase (Lysin CF-301) Against the Most Common Causes of Infective Endocarditis." The findings demonstrate that exebacase has potent activity against all *Staph* species and virulent *Strep* species, including *S. intermedius*, *S. agalactiae* and *S. dysgalactiae*, which are some of the most common causes of infective endocarditis.

- In June 2019, AAC published the Company's manuscript entitled "Postantibiotic and Sub-MIC Effects of Exebacase (Lysin CF-301) Enhance Antimicrobial Activity against *Staphylococcus aureus*." The data demonstrate that sub-MIC concentrations of exebacase during therapeutic use in addition to standard-of-care antibiotics may contribute to efficacy via sustained reductions in bacterial fitness and virulence in a series of *in vitro* studies.

- In April 2019, AAC published the Company's article titled "The Antistaphylococcal Lysin, CF-301, Activates Key Host Factors in Human Blood to Potentiate Methicillin-Resistant *Staphylococcus aureus* Bacteriolysis." The results demonstrate the unique properties of exebacase, which activates dormant host defense factors in human blood, such as human lysozyme, to potentiate bactericidal power against MRSA.

2019 Financial Highlights

- In December 2019 the Company strengthened its balance sheet with the pricing of two separate registered offerings of its common stock for a total of $20 million dollars in addition to a concurrent $3 million private equity placement by Pfizer Inc. Pfizer now has a senior executive serving as a board observer on the Science and Technology Committee of the ContraFect board of directors.

- In June 2019, the Congressionally Directed Medical Research Programs awarded the Company $7.2 million in funding over the course of three years from the Military Infectious Diseases Research Program, United States Army Medical Research and Development Command, to advance its lysin candidate, CF-296, through IND-enabling studies. CF-296 is an engineered variant of exebacase that may be suitable for development as a novel therapy for bone and joint infections caused by *Staph aureus*, such as prosthetic joint infections, which are notoriously poorly responsive to current antibiotics, typically require surgery, and are associated with substantial morbidity including long-term disability.

- In March 2019, the Company announced that the Combating Antibiotic Resistant Bacteria Biopharmaceutical Accelerator (CARB-X) awarded the Company up to $6.94 million in non-dilutive funding to accelerate the development of its newly discovered and proprietary class of amurin peptides as potential therapeutics to treat serious and potentially life-threatening infections, including those caused by antibiotic-resistant gram-negative ESKAPE pathogens. The award commits initial funding up to $1.75 million with the potential to receive an additional $5.19 million from CARB-X contingent on reaching certain project milestones.

- In January 2019, the Company announced that CARB-X awarded the Company $2.3 million in additional non-dilutive funding for the development of lysin therapeutics to treat serious, potentially life-threatening invasive infections caused by antibiotic-resistant *P. aeruginosa*, a virulent gram-negative pathogen.

Fourth quarter and Full Year 2019 Financial Results

- Research and development (R&D) expenses were $3.9 million for the fourth quarter of 2019 compared to $6.7 million in the comparable period in 2018. This decrease was primarily attributable to a reduction in clinical study expenditures as there was no active clinical study during most of the quarter compared to the continuation of the Company's Phase 2 study of exebacase in the fourth quarter of 2018. R&D expenses for the full year 2019 were $18.1 million compared to $22.4 million for the full year 2018. This decrease was again primarily attributable to the reduction in clinical study expenditures as there was no active study during most of 2019 compared to the completion of enrollment and continuing safety follow-up of the Phase 2 study in 2018.

- General and administrative (G&A) expenses were $2.6 million for the fourth quarter of 2019 compared to $2.1 million in the comparable period in 2018. This increase was due primarily to an increase in legal fees for general corporate matters and expansion of the Company's intellectual property portfolio. G&A expenses for the full year 2019 were $9.8 million compared to $8.7 million for the full year 2018. This increase was due primarily to increases in legal fees for general corporate matters and expansion of the Company's intellectual property portfolio, consulting fees for investor and media relations and personnel expenses.

- Net loss was $10.4 million, or a loss of $1.11 per share, for the fourth quarter of 2019 compared to net income of $5.9 million, or income of $0.75 per share, for the comparable period in 2018. The change to a net loss per share includes an $18.5 million, or $1.99 per share, increase in the non-cash charge for the change in fair value of warrant liabilities.

- Net loss for the full year 2019 was $12.8 million, or a loss of $1.54 per share, compared to net loss of $37.7 million, or a loss of $4.95 per share, for the full year 2018. The decrease in net loss per share includes an $21.9 million, or $2.65 per share, decrease in the non-cash charge for the change in fair value of warrant liabilities.

- As of December 31, 2019, ContraFect had cash, cash equivalents and marketable securities of $24.2 million.

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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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 ability to discover and develop DLAs as new medical modalities for the treatment of life-threatening, antibiotic-resistant infections, statements made by Dr. Pomerantz, including whether the Company's new treatment modalities have the potential for superior clinical outcomes, statements regarding the Phase 3 trial design and FDA concurrence, the End-of-Phase 2 meeting with the FDA, data that would be sufficient to support a BLA, Phase 2 topline data, CF-370 data and Aap2-M1 data, statements made regarding the Company balance sheet, financial results and funding sources, ContraFect's ability to address life threatening infections using 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 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 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.

CONTRAFECT CORPORATION
Condensed Balance Sheets

	December 31, 2019	December 31, 2018
Assets		
Current assets:		
Cash and cash equivalents	$ 24,184,140	$ 8,320,317
Marketable securities	—	22,131,936
Prepaid expenses and other current assets	6,575,375	988,779
Total current assets	30,759,515	31,441,052
Property and equipment, net.	1,099,948	1,079,099
Operating lease right-of-use assets	3,042,826	—

Other assets	105,420	355,420
Total assets	$ 35,008,709	$ 32,872,571
Liabilities and stockholders' equity		
Current liabilities	$ 10,057,950	$ 5,797,019
Other liabilities	9,405,853	21,533,292
Total liabilities	19,463,803	27,330,611
Total stockholders' equity	15,544,906	5,541,960
Total liabilities and stockholders' equity	$ 35,008,709	$ 32,872,571

CONTRAFECT CORPORATION
Unaudited Statements of Operations

	Three Months Ended December 31,		Year Ended December 31,	
	2019	**2018**	**2019**	**2018**
	(unaudited)	(unaudited)		
Operating expenses:				
Research and development	$ 3,895,482	$ 6,718,522	$ 18,057,025	$ 22,416,651
General and administrative	2,575,179	2,125,990	9,809,423	8,707,774
Total operating expenses	6,470,661	8,844,512	27,866,448	31,124,425
Loss from operations	(6,470,661)	(8,844,512)	(27,866,448)	(31,124,425)
Other (expense) income:	(3,884,823)	14,780,208	15,071,955	(6,559,999)
Net (loss) income	$ (10,355,484)	$ 5,935,696	$ (12,794,493)	$ (37,684,424)
Net (loss) income per common share:				
Basic	$ (1.11)	$ 0.75	$ (1.54)	$ (4.95)
Diluted	$ (1.11)	$ 0.75	$ (1.54)	$ (4.95)
Weighted average shares:				
Basic	9,300,073	7,940,931	8,283,509	7,606,266
Diluted	9,300,073	7,966,155	8,283,509	7,606,266

The comparability of basic and diluted net loss per share and weighted average shares outstanding was impacted by the Company's follow-on offerings of securities in December 2019 and August 2018.

The Company's financial position as of December 31, 2019 and 2018 and results of operations for the years ended December 31, 2019 and 2018 have been extracted from the Company's audited financial statements included in its Annual Report on Form 10-K filed with the Securities and Exchange Commission. You should refer to the Company's Annual Report on Form 10-K for a complete discussion of financial information.

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