May 15, 2020

ContraFect Reports First Quarter 2020 Financial Results and Provides Business Update

YONKERS, N.Y., May 15, 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 first quarter ended March 31, 2020.

“We began 2020 in stride, enrolling patients into our Phase 3 DISRUPT superiority study of exebacase and then receiving Breakthrough Therapy designation from the FDA for exebacase for the treatment of MRSA bloodstream infections,” said Roger J. Pomerantz, M.D., President, Chief Executive Officer, and Chairman of ContraFect. “We look forward to the prospect of achieving several significant clinical and financial milestones, as we continue to advance our portfolio of potential new treatment modalities throughout the remainder of the year,” he continued.

Q1 2020 Highlights

- In February, the Company announced that that the U.S. Food and Drug Administration (FDA) granted Breakthrough Therapy designation to exebacase for the treatment of methicillin-resistant *Staphylococcus aureus* (MRSA) bloodstream infections (bacteremia), including right-sided endocarditis, when used in addition to standard-of-care (SOC) anti-staphylococcal antibiotics in adult patients. The FDA’s decision was based on the final data from the Phase 2 superiority trial of exebacase. In a pre-specified analysis of patients with MRSA infections, the clinical responder rate at Day 14 among exebacase-treated patients was 42.8 percentage points higher than the responder rate among patients treated with SOC antibiotics alone (74.1% vs 31.3%, respectively, p=0.010). Treatment with exebacase was also associated with a 21-percentage point reduction in the 30-day all-cause mortality (p=0.056), a four-day reduction in length of hospital stay, and meaningful reductions in 30-day hospital readmission rates in MRSA-infected patients. This was the first superiority data set ever shown in MRSA bacteremia over and above the standard of care since vancomycin was approved in 1958.

  Breakthrough Therapy designation is a program designed by the FDA to expedite the

development and review of medicines for serious or life-threatening diseases with preliminary clinical evidence that the investigational therapy may demonstrate substantial improvement on at least one clinically significant endpoint over available therapies.

- In January, the Company announced that the first patient was dosed in the Phase 3 DISRUPT (Direct Lysis of *Staph aureus* Resistant Pathogen Trial) study of exebacase in patients with *Staph aureus* bacteremia, including right-sided endocarditis.

  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.

- The Company also extended early access to exebacase to patients with chronic post-operative prosthetic joint infections (PJIs) in January. This compassionate use program is in collaboration with Dr. Tristan Ferry at the Hôpital de la Croix Rousse in Lyon, France and authorized by the French National Agency for Medicines and Health Products Safety which grants access to individual named patients under Temporary Authorizations for Use.

  The clinical responses of the first four patients who were treated with exebacase, administered intra-articularly were recently detailed in a published abstract in the 30th European Congress of Clinical Microbiology and Infectious Diseases (ECCMID) abstract book. All patients had chronic, relapsing PJIs, with several previous prosthetic knee revisions and other procedures. Two had clinical signs of septic arthritis and the two others had fistula. No adverse events occurred during arthroscopy. After 1 year follow up, the outcome was favorable in the two septic arthritis patients, with disappearance of clinical signs of septic arthritis. The Company believes this is an early indication that exebacase has the potential to be used in patients with relapsing PJIs.

Multiple Presentations at Scientific Conferences

- In March, Cara Cassino, M.D., Chief Medical Officer and Executive Vice President of Research, was the chair of the opening day of the virtual 22nd Annual Superbugs & Superdrugs 2020 Conference. Dr. Cassino also presented the Company's anti-infective portfolio and platform technology of DLAs in her talk, "Exploring Direct Lytic Agents (DLAs) and their potential as a successful disruptive anti-infective technology."

- Dr. Cassino, M.D. also served as a panel member at the invitation of the Food and Drug Administration (FDA) to provide industry perspective at the FDA's March 5th

public workshop entitled “Advancing Animal Models for Antibacterial Drug Development”.

- In January, Dr. Cassino was invited by the organizers of the ASM Biothreats Conference to discuss the potential role of DLAs to combat high consequence biodefense and biologic threats. Dr. Cassino’s talk, “Direct Lytic Agents: Novel Pipeline for Biothreat Defense”, included an overview of the Company’s DLA pipeline, including agents with potential utility against biowarfare threats such as anthrax and other weaponizable pathogens, and also discussed the potential role of exebacase in addressing the downstream threat of hospital-acquired MRSA bacteremia in the setting of a potential bio-threat exposure with mass casualty events.

COVID-19 impact on Company operations

- During the quarter ended March 31, 2020, the novel coronavirus disease, COVID-19, was declared a pandemic and spread to multiple regions across the globe, including the United States and Europe. The outbreak and government measures taken in response have impacted, both directly and indirectly, the Company’s business. The full extent of the impact to the Company’s business, results of operations and financial condition, including expenses, research and development costs and clinical trial progress will depend on future developments that are highly uncertain, including as a result of new information that may emerge.

- The Company has adjusted its business operations in response to COVID-19, with a majority of its employees working remotely, and as a result, incurred some delays in certain research activities. COVID-19 has not affected the Company’s supply chain or its ability to supply the Phase 3 DISRUPT study of exebacase. Patient enrollment is ongoing and clinical trial sites continue to open since the Phase 3 DISRUPT trial has potential for significant benefit in *Staph aureus* bacteremia, a serious and life-threatening condition. The Company has experienced some delays in new patient enrollment in the Phase 3 DISRUPT study due to the diversion of healthcare resources resulting from the COVID-19 pandemic in certain high impact areas. The Company will continue to monitor the potential impacts of COVID-19 on its business.

First Quarter 2020 Financial Results

- Research and development (R&D) expenses were $5.1 million for the first quarter of 2020 compared to $4.1 million in the comparable period in 2019. This increase was primarily attributable to an increase in spending related to manufacturing of drug supply for the exebacase program and for process development costs for our CF-296 program. These increases were partially offset by an increase in the amounts recognized to be reimbursed under the Company’s grants, which reduce research and development expenses.

- General and administrative (G&A) expenses were $3.0 million for the first quarter of 2020 compared to $2.3 million in the comparable period in 2019. This increase was primarily attributable to an increase in administrative headcount and related personnel costs and expenses incurred for intellectual property and general corporate legal fees.

- Net loss was $7.6 million, or a loss of $0.49 per share, for the first quarter of 2020 compared to net income of $11.6 million, or income of $1.46 per share, for the comparable period in 2019. The change to a net loss per share includes an $17.4 million, or $1.13 per share, decrease in the non-cash gain for the change in fair value of warrant liabilities.

- As of March 31, 2020, ContraFect had cash, cash equivalents and marketable securities of $16.7 million.

About ContraFect

ContraFect is a 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. 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 *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. Exebacase, currently being studied in a pivotal Phase 3 clinical study, was granted Breakthrough Therapy designation by the FDA 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.

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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 will achieve significant milestones and advance its portfolio of new treatment modalities through the remainder of the year, statements made regarding Breakthrough Therapy designation and the Phase 3 DISRUPT study, statements made regarding the compassionate use program, treatment results, and whether the outcome is an early indication that exebacase has the potential to be used in patients with relapsing PJIs,

whether the COVD-19 pandemic impacted the Company directly and indirectly, statements made regarding how COVID-19 has affected the Company's research and development activities, supply chain or ability to supply the Phase 3 trial, clinical trial site opening and patient enrollment, whether the Company will continue to monitor the potential impacts of COVID-19 on its business, the Company's financial results, financial position, balance sheets and statements of operations, 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 Consolidated Balance Sheets

	March 31, 2020	December 31, 2019
	(unaudited)	(audited)
Assets		
Current assets:		
Cash and cash equivalents	$ 10,631,943	$ 24,184,140
Marketable securities	6,018,894	—
Prepaid expenses and other current assets	5,632,510	6,575,375
Total current assets	22,283,347	30,759,515
Property and equipment, net	1,052,169	1,099,948
Operating lease right-of-use assets	2,987,806	3,042,826
Other assets	105,420	105,420
Total assets	$ 26,428,742	$ 35,008,709
Liabilities and stockholders' equity		
Current liabilities	$ 8,903,703	$ 10,057,950
Other liabilities	8,916,518	9,405,853
Total liabilities	17,820,221	19,463,803
Total stockholders' equity	8,608,521	15,544,906

Total liabilities and stockholders' equity	$ 26,428,742	$ 35,008,709

CONTRAFECT CORPORATION
Unaudited Consolidated Statements of Operations

	Three Months Ended March 31,	
	2020	**2019**
Operating expenses		
Research and development	$ 5,104,441	$ 4,107,140
General and administrative	2,959,900	2,254,593
Total operating expenses	8,064,341	6,361,733
Loss from operations	(8,064,341)	(6,361,733)
Other income:		
Interest income	70,022	149,119
Change in fair value of warrant liabilities	415,833	17,799,629
Total other income	485,855	17,948,748
Net (loss) income	$ (7,578,486)	$ 11,587,015
Per share information:		
Net (loss) income per share of common stock, basic and diluted	$ (0.49)	$ 1.46
Basic and diluted weighted average shares outstanding	15,332,042	7,940,931

The Company's financial position as of March 31, 2020 and results of operations for the three months ended March 31, 2020 and 2019 have been extracted from the Company's Quarterly Report on Form 10-Q filed with the Securities and Exchange Commission. The Company's financial position as of December 31, 2019 has 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 on March 18, 2020. You should refer to both the Company's Quarterly Report on Form 10-Q and its Annual Report on Form 10-K for a complete discussion of financial information.

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ContraFect
MOLECULAR TREATMENTS FOR INFECTIOUS DISEASE

Source: ContraFect Corporation