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BioCryst Announces Positive Study Results for BCX4430 Delayed Treatment of Ebola Virus Infection in a Non-Human Primate Model

RESEARCH TRIANGLE PARK, N.C., Sept. 07, 2016 (GLOBE NEWSWIRE) -- [BioCryst Pharmaceuticals, Inc.](#) (NASDAQ:BCRX) today announced positive results from a proof-of-concept study of its broad spectrum antiviral, [BCX4430](#), for the delayed treatment of Ebola virus infection in rhesus macaques.

The goals of this 28-day study were to assess the effect of different dosing regimens of BCX4430 administered by i.m. injection on survival in rhesus macaques with established Ebola virus disease. The study consisted of three treatment groups of six animals each treated with different BCX4430 dosing schedules and one control group of six animals.

"USAMRIID was pleased to work with our partners at BioCryst to advance the understanding of the efficacy of BCX4430. We are encouraged by the favorable results demonstrating significant efficacy of BCX4430 under delayed treatment scenarios," said Dr. Travis K. Warren, Principal Investigator, USAMRIID. "The available human safety data and new efficacy data position BCX4430 as a highly promising therapeutic that could potentially be used to treat people with Ebola virus disease when future outbreaks arise."

Following inoculation of virus on Day 0, six of 6 (100%) animals survived after receiving 100 mg/kg BCX4430 twice on day 2, followed by 25 mg/kg twice daily for an additional nine days, compared to none of 6 controls ($p < 0.001$). Animals treated with the same loading and maintenance dose regimen of BCX4430, but starting on day 3, also showed improved survival (4 of 6, 67%, $p = 0.005$), as did animals treated with 25 mg/kg of BCX4430 twice daily for 14 days starting on day 2 (4 of 6, 67%, $p = 0.005$).

"These study results add to the growing body of evidence of the potential utility of BCX4430 for treatment of a broad range of serious emerging viral infections, including Ebola virus disease and Zika virus disease," said [Dr. William P. Sheridan](#), SVP and Chief Medical Officer, BioCryst Pharmaceuticals. "We look forward to completing the studies required to satisfy requirements for Emergency Use Readiness and full regulatory approval of this novel broad-spectrum antiviral drug."

This project is substantially funded with Federal funds from the National Institute of Allergy and Infectious Diseases (NIAID), National Institutes of Health and the Department of Health and Human Services and [the Biomedical Advanced Research and Development Authority \(BARDA\)](#) within the U.S. Department of Health and Human Services' [Office of the Assistant Secretary for Preparedness and Response](#). In September 2013, NIAID awarded BioCryst a contract for the development of BCX4430 as a potential treatment for filovirus diseases, HHSN272201300017C, with a current contract value of \$39.5 million if all contract options are exercised. In March 2015, [BARDA](#) awarded BioCryst a contract, HHSO100201500007C, for the continued development of BCX4430 as a potential treatment for filovirus diseases with a current contract value of \$39.1 million if all contract options are exercised.

About BCX4430

BCX4430 is a broad spectrum antiviral in advanced development under the Animal Rule for the first indication of treatment of Ebola virus disease. A Phase 1 clinical safety and pharmacology study in healthy subjects has been completed, and in animal studies, BCX4430 has demonstrated survival benefits against a variety of serious pathogens, including Ebola, Marburg, Yellow Fever and Zika viruses. BCX4430 has also demonstrated broad-spectrum activity in vitro against more than 20 RNA viruses in nine different families, including filoviruses, togaviruses, bunyaviruses, arenaviruses, paramyxoviruses, coronaviruses and flaviviruses. BioCryst is developing BCX4430 in collaboration with U.S. Government Agencies.

About USAMRIID

USAMRIID's mission is to provide leading edge medical capabilities to deter and defend against current and emerging biological threat agents. Research conducted at USAMRIID leads to medical solutions-vaccines, drugs, diagnostics, and information-that benefit both military personnel and civilians. The Institute, located at Fort Detrick, MD., is the only Department of Defense laboratory equipped to safely study highly hazardous viruses, including Ebola, at Biosafety Level 4 (maximum containment). USAMRIID is a subordinate laboratory of the U.S. Army Medical Research and Materiel Command.

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About BioCryst Pharmaceuticals

BioCryst Pharmaceuticals designs, optimizes and develops novel small molecule drugs that block key enzymes involved in rare diseases. BioCryst currently has several ongoing development programs: BCX7353 and second generation oral inhibitors of plasma kallikrein for hereditary angioedema, and BCX4430, a broad spectrum viral RNA polymerase inhibitor that is a potential treatment for filoviruses. RAPIVAB™ (peramivir injection), a viral neuraminidase inhibitor for the treatment of influenza is BioCryst's first approved product and is currently marketed in the U.S., Japan, and Korea. Post -marketing commitment development activities are ongoing as well as activities to support regulatory approvals in other territories. For more information, please visit the Company's website at www.BioCryst.com.

Forward-Looking Statements

This press release contains forward-looking statements, including statements regarding future results, performance or achievements. These statements involve known and unknown risks, uncertainties and other factors which may cause BioCryst's actual results, performance or achievements to be materially different from any future results, performances or achievements expressed or implied by the forward-looking statements. These statements reflect our current views with respect to future events and are based on assumptions and are subject to risks and uncertainties. Given these uncertainties, you should not place undue reliance on these forward-looking statements. Some of the factors that could affect the forward-looking statements contained herein include: that the Company or its licensees may not commence as expected additional pre-clinical studies or human clinical trials; that the planned studies may not be successful or may not be successfully completed; that the FDA may require additional studies beyond those planned for BCX4430, or may not provide regulatory clearances which may result in delay of planned clinical trials, or may impose a clinical hold on BCX4430, or withhold market approval for BCX4430; that the Company may not be able to obtain additional funding for BCX4430 development; that government funding or other contracts for BCX4430 may have certain terms and conditions, including termination provisions, that subject the Company to additional risks; and/or that the Company may lose current funding for the program. Please refer to the documents BioCryst files periodically with the Securities and Exchange Commission, specifically BioCryst's most recent Annual Report on Form 10-K, Quarterly Reports on Form 10-Q, and current reports on Form 8-K, all of which identify important factors that could cause the actual results to differ materially from those contained in BioCryst's projections and forward-looking statements.

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