BioCryst Completes Phase 1 Clinical Trial of Galidesivir

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RESEARCH TRIANGLE PARK, N.C., May 09, 2019 (GLOBE NEWSWIRE) -- BioCryst Pharmaceuticals, Inc. (NASDAQ:BCRX) today announced the completion of a randomized, placebo-controlled Phase 1 clinical trial to evaluate intravenous (IV) galidesivir in healthy volunteers. In the trial, galidesivir was generally safe and well tolerated.

This placebo-controlled trial evaluated the safety, tolerability and pharmacokinetics of escalating doses of galidesivir in four single-dose cohorts of 5mg/kg, 10 mg/kg, 15 mg/kg and 20 mg/kg, with a total of 24 volunteers receiving galidesivir by IV infusion. Drug exposures (C_{max} and AUC) at the highest dose were 20,500 ng/mL and 44,600 hr.ng/mL, similar to or greater than drug exposures needed in nonclinical galidesivir treatment experiments in Marburg virus disease and Yellow Fever.

"These results for the IV route of administration of galidesivir, which build on a previous successful Phase 1 trial for the IM route, support its continued development for serious and life-threatening infections from RNA viruses. We appreciate the government's continued financial support for and collaboration on the program as we advance galidesivir into a trial in patients with Yellow Fever in Brazil during the upcoming Yellow Fever season," said Dr. William Sheridan, chief medical officer of BioCryst.

Yellow Fever is a serious infectious disease, endemic to tropical areas of Africa and Central and South America, and responsible for up to 170,000 severe cases and up to 60,000 deaths annually, according to the World Health Organization. There is no approved treatment for Yellow Fever and immunization has been hampered by global Yellow Fever vaccine shortages.

In September 2018, BioCryst announced that the National Institute of Allergy and Infectious Diseases (NIAID), part of the National Institutes of Health, had awarded BioCryst an additional $3.5 million to support clinical trials of galidesivir in patients with Yellow Fever.

The galidesivir development program is substantially funded with federal funds from NIAID and by the Biomedical Advanced Research and Development Authority (BARDA).

BioCryst has global rights to galidesivir, a broad-spectrum antiviral drug in development to treat Marburg virus disease and Yellow Fever. In a previous Phase 1 trial of clinical safety and pharmacokinetics in healthy subjects, intramuscularly (IM) administered galidesivir was safe and well tolerated. In animal studies, galidesivir also has demonstrated survival benefits against several serious viral infections including Ebola, Marburg, Yellow Fever and Zika.

Since September 2013, NIAID has supported BioCryst in developing galidesivir as a therapeutic for Ebola and Marburg viruses under Contract No. HHSN272201300017C. The NIAID development contract totals $43.0 million.

Since March 2015, BARDA has supported the galidesivir development program under contract HHSO100201500007C for the continued development of galidesivir as a potential treatment for filoviruses. The total BARDA contract value to advance the program through toxicology studies and manufacturing work to support a new drug application is $39.1 million if all contract options are exercised.

About Galidesivir (BCX4430)
Galidesivir is a broad-spectrum antiviral in advanced development for the treatment Marburg virus disease and Yellow Fever. Phase 1 clinical safety and pharmacokinetics trials of galidesivir by both intravenous and intramuscular routes of administration in healthy subjects have been completed and, in animal studies, galidesivir has demonstrated survival benefits against a variety of serious pathogens, including Ebola, Marburg, Yellow Fever and Zika viruses. Galidesivir 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 galidesivir in collaboration with U.S. government agencies and other institutions.

About BioCryst Pharmaceuticals
BioCryst Pharmaceuticals discovers novel, oral small-molecule medicines that treat rare diseases in which significant unmet medical needs exist and an enzyme plays a key role in the biological pathway of the disease. BioCryst has several ongoing development programs including BCX7353, an oral treatment for hereditary angioedema, BCX9930, an oral Factor D inhibitor for the treatment of complement-mediated diseases, galidesivir, a potential treatment for Marburg virus disease and Yellow Fever, and a preclinical program to develop oral ALK-2 inhibitors for the treatment of fibrodysplasia ossificans progressiva. RAPIVAB® (peramivir injection), a viral neuraminidase inhibitor for the treatment of influenza, is BioCryst's first approved product and has received regulatory approval in the U.S., Canada, Australia, Japan, Taiwan, Korea and the European Union. Post-marketing commitments for RAPIVAB are ongoing. 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 BioCryst or its licensees may not be able to enroll the required number of subjects in planned clinical trials of galidesivir and that such clinical trials may not be successfully completed; that the Company or its licensees may not commence additional pre-clinical studies or human clinical trials may not be commenced as expected; that the FDA may require additional studies

beyond those planned for galidesivir, or may not provide regulatory clearances which may result in delay of planned clinical trials, or may impose a clinical hold on galidesivir, or withhold market approval for product candidates; that the Company may not be able to obtain additional funding for galidesivir; that government funding or other contracts for galidesivir may have certain terms and conditions, including termination provisions, that subject the Company to additional risks; that the Company may lose current funding for the program; that its actual financial results may not be consistent with its expectations, including that operating expenses and cash usage may not be within management's expected ranges. 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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Contact:
John Bluth
+1 919 859 7910
jbluth@biocryst.com