



## BioCryst Initiates Phase 1 Clinical Trial of Galidesivir

January 2, 2019

RESEARCH TRIANGLE PARK, N.C., Jan. 02, 2019 (GLOBE NEWSWIRE) -- [BioCryst Pharmaceuticals, Inc.](http://www.biocryst.com) (NASDAQ:BCRX) today announced the dosing of the first subject in a randomized, placebo-controlled phase 1 clinical trial to evaluate intravenous (IV) galidesivir in healthy volunteers.

The main goals of this trial are to evaluate the safety, tolerability and pharmacokinetics of escalating doses of galidesivir in healthy subjects. Up to four single-dose cohorts will be evaluated with a total of up to 32 volunteers participating.

The galidesivir development program is substantially funded with federal funds from the National Institute of Allergy and Infectious Diseases (NIAID), part of the National Institutes of Health, 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, intra-muscularly administered galidesivir was safe and well tolerated. In animal studies, galidesivir also has demonstrated survival benefits against several serious viral infections including Marburg, Ebola, Yellow Fever and Zika viruses.

"We appreciate the financial support of the federal government for the development of galidesivir as we continue to advance its evaluation as a treatment option for highly pathogenic viral infections. Data from this new trial and potential future studies could support the inclusion of galidesivir in the Strategic National Stockpile," said Jon Stonehouse, chief executive officer of BioCryst.

Since September 2013, NIAID has supported BioCryst in developing galidesivir as a therapeutic for Ebola and Marburg viruses under Contract No. HHSN272201300017C. In September 2018, BioCryst announced that NIAID had awarded BioCryst an additional \$3.5 million to support clinical trials of galidesivir in patients with Yellow Fever. 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. A phase 1 clinical safety and pharmacokinetics trial of galidesivir by intramuscular injection in healthy subjects has 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, 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<sup>®</sup> (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](http://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.

BCRXW

**Contact:**

John Bluth

+1 919 859 7910

[jbluth@biocryst.com](mailto:jbluth@biocryst.com)