



## BioCryst Begins Clinical Trial with Galidesivir for Treatment of Patients with COVID-19

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RESEARCH TRIANGLE PARK, N.C., April 09, 2020 (GLOBE NEWSWIRE) -- [BioCryst Pharmaceuticals, Inc.](#) (Nasdaq:BCRX) today announced that the company has opened enrollment into a randomized, double-blind, placebo-controlled clinical trial to assess the safety, clinical impact and antiviral effects of galidesivir in patients with COVID-19. The trial (NCT03891420) is being funded by the [National Institute of Allergy and Infectious Diseases \(NIAID\)](#), part of the National Institutes of Health.

Galidesivir is an investigational broad-spectrum antiviral drug that was safe and well tolerated in previously reported Phase 1 trials in healthy subjects. Galidesivir has demonstrated broad-spectrum activity *in vitro* against more than 20 RNA viruses in nine different families, including the coronaviruses that cause MERS and SARS.

In the COVID-19 trial, efficacy measures include time to clinical improvement, time to hospital discharge, time to undetectable levels (as measured by polymerase chain reaction (PCR) in respiratory specimens) of SARS-CoV-2, the virus that causes COVID-19, and all-cause mortality.

The trial will be conducted in Brazil under a U.S. investigational new drug application, and the protocol also has been approved by the Agência Nacional de Vigilância Sanitária (ANVISA) and the Brazilian National Ethics Committee (CONEP).

"Galidesivir has been safe and well-tolerated in Phase 1 studies, and, as a potent broad-spectrum antiviral medicine, we are hopeful that we will see a benefit in patients with COVID-19. This trial is part of the scientific community's effort to urgently find effective treatments for patients in this global health emergency," said Dr. William Sheridan, chief medical officer of BioCryst.

"We have begun to see COVID-19 cases in Brazil, and we have a good opportunity to enroll and treat patients earlier in their disease course to determine if galidesivir can benefit patients with COVID-19," said Dr. Esper Kallas, infectious diseases specialist and professor of medicine at the School of Medicine, University of São Paulo, and principal investigator of the COVID-19 clinical trial with galidesivir.

### Galidesivir COVID-19 Trial Design

Part 1 of the trial will enroll 24 hospitalized adults diagnosed with moderate to severe COVID-19 confirmed by PCR. Three cohorts of eight patients will be randomized to receive intravenous (IV) galidesivir (n=6) or placebo (n=2) every 12 hours for 7 days. Upon completion of part 1 of the trial, an optimized dosing regimen of galidesivir will be selected for part 2 of the trial, based on part 1 results including safety, viral load reduction in respiratory tract secretions, improvement in COVID-19 signs and symptoms and clinical manifestations, and mortality. In part 2 of the trial, up to 42 hospitalized patients with COVID-19 will be randomized 2:1 to receive IV galidesivir or placebo. After treatment, the patients will remain hospitalized until resolution of COVID-19 symptoms allows release. All patients will be followed for mortality through Day 56.

The galidesivir development program is substantially funded with federal funds from NIAID and by the Biomedical Advanced Research and Development Authority (BARDA). Since September 2013, NIAID has supported BioCryst in developing galidesivir as a therapeutic for Ebola and Marburg viruses under contract HHSN272201300017C. 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.

### About Galidesivir (BCX4430)

Galidesivir, a broad-spectrum antiviral drug, is an adenosine nucleoside analog that acts to block viral RNA polymerase. It is in advanced development for the treatment of COVID-19, 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. In animal studies, galidesivir has demonstrated activity 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 coronaviruses, filoviruses, togaviruses, bunyaviruses, arenaviruses, paramyxoviruses, 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 berotralstat (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 COVID-19, Marburg virus disease and Yellow Fever, and BCX9250, an ALK-2 inhibitor 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, performance 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 developing and manufacturing any product candidate, including galidesivir, may take longer or may be more expensive than planned; that funding for the continued development and manufacture of galidesivir may not be available; that ongoing and

future preclinical and clinical studies with galidesivir may not have positive results; that BioCryst may not be able to enroll the required number of subjects in planned clinical trials of product candidates, including galidesivir; that BioCryst may not advance human clinical trials with product candidates, including galidesivir, as expected; that the FDA, EMA, PMDA, ANVISA, CONEP or other applicable regulatory or ethics agency decisions may be negatively impacted by the COVID-19 pandemic; that such agencies may require additional studies beyond the studies planned for product candidates, or may not provide regulatory clearances which may result in delay of planned clinical trials, or may impose a clinical hold with respect to such product candidates, or withhold market approval for product candidates; that actual financial results may not be consistent with expectations, including that 2020 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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