Galidesivir Stops Zika Viral Replication in Primate Model

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—Data published in Science Translational Medicine —

—Broad-spectrum antiviral activity against multiple RNA viruses—

RESEARCH TRIANGLE PARK, N.C., June 10, 2020 (GLOBE NEWSWIRE) -- BioCryst Pharmaceuticals, Inc. (Nasdaq:BCRX) today announced new data published in *Science Translational Medicine* show, in a primate model, that galidesivir was safe, provided post-exposure prevention of Zika viral replication across a range of doses, and rapidly reduced viral loads to undetectable levels when dosed up to 72 hours after infection with Zika virus.

“Galidesivir reduced Zika virus replication from the first dose administered without impairing the adaptive immune response that protects against subsequent infection. These data provide an encouraging foundation for studying SARS-CoV-2, another RNA-replicating virus, in this same animal species,” said James B. Whitney, Ph.D., assistant professor of medicine at Harvard Medical School and lead author of the study.

“The rapid reduction in Zika viral load we see in this robust animal model further demonstrates the broad antiviral potential of galidesivir against multiple pathogens. The current COVID-19 pandemic has reinforced the urgent global need for effective broad-spectrum antiviral therapies to combat these outbreaks,” said Dr. William Sheridan, chief medical officer of BioCryst.

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. A Phase 1 trial to assess the safety, clinical impact and antiviral effects of galidesivir in patients with COVID-19 is currently enrolling patients across multiple sites in Brazil.

Zika Study Details
In the Zika virus study of galidesivir, 70 Rhesus macaques were studied with different routes of infection, different doses of galidesivir, and galidesivir treatment initiated at different time points after infection. Endpoints included Zika virus RNA quantity in plasma, saliva, urine, and cerebrospinal fluid (CSF), and a variety of immunologic measurements, including antibody seroconversion to Zika virus. Galidesivir was safe and showed robust antiviral activity at all stages of Zika infection and at multiple different doses. Zika-infected animals that were treated with galidesivir developed an immune response to Zika that was protective against subsequent Zika re-challenge.

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® (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, 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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