NIAID Awards BioCryst New $44 Million Contract to Advance Development of Galidesivir

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RESEARCH TRIANGLE PARK, N.C., Aug. 31, 2020 (GLOBE NEWSWIRE) -- BioCryst Pharmaceuticals, Inc. (Nasdaq:BCRX) today announced that the National Institute of Allergy and Infectious Diseases (NIAID), part of the National Institutes of Health, has awarded BioCryst a new contract (75N93020C00055) totaling $44 million, and has added approximately $3 million to its existing contract (HHSN272201300017C), to support the development of galidesivir.

The additional funds under these performance-based contracts support:

- The completion of parts 1 and 2 of an ongoing clinical trial of galidesivir in Brazil
- Conducting a phase 2 clinical trial of galidesivir in non-hospitalized COVID-19 patients at high risk for developing severe disease and complications of COVID-19
- Conducting a clinical pharmacology trial of galidesivir to determine appropriate dosing in patients with renal impairment
- Increasing the supply of galidesivir

“With this additional investment in galidesivir by NIAID, we are now positioned to further evaluate and advance galidesivir through additional clinical trials in different settings beyond hospitalized patients, and to accelerate our manufacturing activities to increase drug supply,” said Jon Stonehouse, chief executive officer of BioCryst.

“We appreciate the financial investment the government continues to make in the galidesivir program. We believe broad-spectrum antivirals, like galidesivir, are critical to combat both the current COVID-19 pandemic and threats from future viruses,” Stonehouse added.

Galidesivir is an investigational broad-spectrum antiviral drug that was safe and well tolerated in previous 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.

The review of unblinded data from part 1 of an ongoing phase 1 trial (NCT03891420) to assess the safety (primary endpoint), clinical impact and antiviral effects of galidesivir in patients with COVID-19, and a decision to choose a dose and advance into part 2 of the trial, are expected to occur in the fourth quarter of 2020.

Additionally, non-human primate studies and supporting *in vitro* studies are underway to assess the activity of galidesivir against SARS-CoV-2, the virus that causes COVID-19.

The galidesivir development program is substantially funded with federal funds from NIAID and by Biomedical Advanced Research and Development Authority (BARDA), part of the Office of the Assistant Secretary for Preparedness and Response in the U.S. Department of Health and Human Services. Since September 2013, NIAID has supported BioCryst in developing galidesivir as broad-spectrum antiviral therapeutic 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 broad- spectrum antiviral treatment for filoviruses. In addition to the new contract award from NIAID, there is currently approximately $27 million remaining on the existing BARDA contract.

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.

Part 1 of an ongoing phase 1 trial (NCT03891420) to assess the safety (primary endpoint), clinical impact and antiviral effects of galidesivir in patients with COVID-19 is currently enrolling 24 hospitalized adults diagnosed with moderate to severe COVID-19 confirmed by PCR. In part 1, three cohorts of eight patients are randomized to receive intravenous (IV) galidesivir (n=6) or placebo (n=2) every 12 hours for seven 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. 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.

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 ORLADEYO™ (berotralstat), 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 BioCryst's plans and expectations for its galidesivir development program. These statements involve known and unknown risks, uncertainties and other factors which may cause actual results and developments of such program to be materially different from any future results or developments expressed or implied by the forward-looking statements. These statements reflect our current views and are based on assumptions and 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: NIAID's ability to determine not to exercise its options under the new contract or to terminate the contract at any time, causing BioCryst not to realize the aggregate value of the contract; funding for galidesivir under government contracts is dependent on the progress toward, and the achievement of, developmental milestones; the ongoing COVID-19 pandemic could create challenges in all aspects of BioCryst's business, including without limitation delays, stoppages, difficulties and increased expenses with respect to BioCryst's and its partners' development, regulatory processes and supply chains, negatively impact BioCryst's ability to access the capital or credit markets to finance its operations, or have the effect of heightening many of the risks described herein or in the documents BioCryst files periodically with the Securities and Exchange Commission; 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; BioCryst may not be able to enroll the required number of subjects in planned clinical trials of product candidates, including galidesivir; BioCryst may not advance human clinical trials with product candidates, including galidesivir, as expected; and the FDA, or other applicable regulatory agency may require additional studies beyond the studies planned for product candidates, may not provide regulatory clearances which may result in delay of planned clinical trials, may impose a clinical hold with respect to such product candidates, or may withhold market approval for product candidates. 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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