



BioCryst Receives Additional \$3.5 Million to Fund Clinical Trials of Galidesivir in Yellow Fever

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RESEARCH TRIANGLE PARK, N.C., Sept. 17, 2018 (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 an additional \$3.5 million to support clinical trials of galidesivir in patients with yellow fever. Yellow fever represents a significant unmet medical need and a new potential use of galidesivir.

With this additional \$3.5 million contract amendment, the NIAID development contract for galidesivir now totals \$43.0 million.

BioCryst has global rights to galidesivir, a broad-spectrum antiviral drug in development for the treatment of Marburg and Ebola viral diseases. In a phase 1 trial of clinical safety and pharmacokinetics in healthy subjects, galidesivir was safe and well tolerated. In animal studies, galidesivir also has demonstrated survival benefits against Marburg, Ebola, yellow fever and Zika viruses.

With the additional NIAID funding, BioCryst plans to assess the safety, tolerability, pharmacokinetics and effectiveness of galidesivir in human subjects with yellow fever, and to determine a safe and effective dose for further evaluation of galidesivir in Marburg or Ebola infection.

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 Brazil, recent seasonal outbreaks of yellow fever, which have extended into urban areas, have put more than 35 million people at risk for contracting the disease. The Brazilian Ministry of Health has confirmed 2,043 cases and 676 deaths due to yellow fever since December 2016.

"We appreciate the NIAID's expanded support for galidesivir, which allows us to evaluate our broad-spectrum antiviral in clinical trials in patients suffering from yellow fever. This program could prove to be very valuable in the overall evaluation of galidesivir for inclusion in the Strategic National Stockpile," said Jon Stonehouse, chief executive officer of BioCryst.

The galidesivir development program project is substantially funded by the NIAID and the Biomedical Advanced Research and Development Authority (BARDA), a part of HHS's Office of the Assistant Secretary for Preparedness and Response. Since September 2013, NIAID has supported BioCryst, making significant advances toward developing galidesivir as a therapeutic for Ebola virus disease and Marburg virus disease under contract number HHSN272201300017C. Since March 2015, BARDA has supported the galidesivir development program under contract number HHSO100201500007C, for the continued development of galidesivir as a potential treatment for filoviruses. The total BARDA contract value to advance the program through new drug application enabling toxicology studies and manufacturing is \$39.1 million, if all contract options are exercised.

About Galidesivir (BCX4430)

Galidesivir is a broad-spectrum antiviral in advanced development under the Animal Rule for the treatment of Marburg and Ebola viral diseases. A phase 1 clinical safety and pharmacokinetics trial 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 designs, optimizes and develops novel small-molecule medicines that address both common and rare conditions. BioCryst has several ongoing development programs including BCX7353, an oral treatment for hereditary angioedema, galidesivir, a potential treatment for filoviruses, 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 additional funding will be required for further development of galidesivir, which additional funding may not be awarded or available; that the development of galidesivir may take longer than expected; that the planned clinical trials or other development programs of galidesivir for the treatment of yellow fever, Marburg virus disease, Ebola virus disease or other potential indications may be unsuccessful or may not be completed; that galidesivir may not be approved by regulatory agencies or purchased by any government agency; and that government contracts contain certain terms and conditions, including termination provisions, that subject the company to additional risks. 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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