



BioCryst Provides Update Regarding Peramivir for Influenza

- Responds to Request for Proposal from U.S. Government
- Initiates Phase 3 studies for patients hospitalized with influenza

BIRMINGHAM, Ala., Sept 30, 2009 /PRNewswire-FirstCall via COMTEX News Network/ -- BioCryst Pharmaceuticals, Inc. (Nasdaq: BCRX) today announced that it has delivered a written response to the request for proposal (RFP) announced on September 21, 2009 from the U.S. Department of Health & Human Services (HHS) for the supply of intravenous (i.v) peramivir for the treatment of critically ill influenza patients under Emergency Use Authorization (EUA). BioCryst management intends to provide an update once the RFP process has reached a conclusion.

In addition, BioCryst announced it is initiating two Phase 3 studies of i.v. peramivir for the treatment of hospitalized patients with serious influenza. These studies are intended to support U.S. regulatory approval of peramivir as a treatment for influenza. Expenses for these Phase 3 studies are covered under the recently modified \$180 million HHS/Biomedical Advanced Research and Development Authority (BARDA) contract to develop peramivir for the treatment of influenza.

"The novel H1N1 2009 virus is already producing significant morbidity and mortality within North America, and I expect the burden on the healthcare system to increase in the coming weeks," said Michael Ison, M.D. MS, Assistant Professor at Northwestern University Feinberg School of Medicine and lead investigator for one of the studies. "This Phase 3 study will provide an important opportunity to evaluate peramivir in an area of unmet medical need for seriously ill patients in the hospital setting."

According to the U.S. Centers for Disease Control & Prevention (CDC), on average 5 to 20 percent of the population gets the flu in the U.S.; more than 200,000 people are hospitalized from flu complications and about 36,000 people die from flu-related causes.

"BioCryst is pleased to be able to proceed with the first phase 3 studies of an anti-viral agent ever conducted in influenza patients requiring hospitalization," said Dr. William P. Sheridan, Chief Medical Officer at BioCryst. "The need for such studies is clear; there are currently no anti-viral agents approved for this seriously ill patient population, and no intravenous or injectable forms of any anti-viral agent are approved for any influenza indication."

One Phase 3 study is a multicenter, randomized, double-blind, controlled study to evaluate the efficacy and safety of i.v. peramivir administered once-daily for five days in addition to standard of care (SOC), compared to standard of care alone, in adults and adolescents who are hospitalized due to serious influenza. The other Phase 3 study is an open-label, randomized study of the anti-viral activity, safety and tolerability of i.v. peramivir 600 mg administered once-daily compared with split doses twice-daily for five days in adult and adolescent hospitalized subjects with confirmed or suspected influenza infection. The combined enrollment target for these studies is approximately 700 patients. Further details regarding these Phase 3 study designs are available at clinicaltrials.gov at this link:

<http://www.clinicaltrials.gov/ct2/results?term=Peramivir+HHS+Phase+3&recr=Open>

About peramivir

Peramivir is an anti-viral agent that was discovered by BioCryst which inhibits the interactions of influenza neuraminidase, an enzyme which is critical to the spread of influenza within a host. In laboratory tests, peramivir has shown activity against pandemic H1N1 swine flu origin viral strains. Peramivir has been studied in patients with complicated and uncomplicated influenza. BioCryst's partner, Shionogi & Co., Ltd. is currently preparing to file for regulatory approval in Japan this year.

About Influenza

Influenza (the flu) is a contagious respiratory illness caused by [influenza viruses](#). It can cause mild to severe illness, and at times can lead to death. According to the CDC, on average 5 to 20 percent of the population gets the flu in the U.S.; more than 200,000 people are hospitalized from flu complications and about 36,000 people die from flu-related causes.

More information is available at:

<http://www.cdc.gov/flu/>

<http://www.hhs.gov/pandemicflu/plan/pdf/HHSPandemicInfluenzaPlan.pdf>

About BioCryst

BioCryst Pharmaceuticals designs, optimizes and develops novel small-molecule pharmaceuticals that block key enzymes involved in infectious diseases, cancer and inflammatory diseases. BioCryst has progressed two novel compounds into late-stage pivotal clinical trials; peramivir, an anti-viral for influenza, and forodesine, a purine nucleoside phosphorylase (PNP) inhibitor for cutaneous T-cell lymphoma (CTCL). Utilizing crystallography and structure-based drug design, BioCryst continues to discover additional compounds and to progress others through pre-clinical and early development to address the unmet medical needs of patients and physicians. The Company's strategic alliances with the U.S. Department of Health and Human Services, Shionogi & Co., Ltd., Green Cross Corporation and Mundipharma International Holdings Limited validate its scientific foundation and the utility of its product candidates. For more information, please visit the Company's Web site 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 our 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 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 peramivir may not receive emergency use authorization; that the U.S. government and ex-U.S. governments may choose not to issue a request for peramivir to treat influenza or such requests, if any, may not result in an order or such order, if any, may not be profitable for BioCryst; that to the extent peramivir is used as a treatment for H1N1 flu (or other strains of flu), there can be no assurance that it will prove effective; that HHS may further condition, reduce or eliminate future funding of the peramivir program; that ongoing peramivir clinical trials or our peramivir program in general may not be successful; that BioCryst or its licensees may not commence as expected additional human clinical trials with our product candidates; that our product candidates may not receive required regulatory clearances from the FDA; that ongoing and future pre-clinical and clinical development may not have positive results; that we or our licensees may not be able to continue future development of our current and future development programs; that our development programs and partnerships may never result in future product, license or royalty payments being received by BioCryst; that BioCryst may not be able to retain its current pharmaceutical and biotechnology partners for further development of its product candidates or it may not reach favorable agreements with potential pharmaceutical and biotechnology partners for further development of its product candidates; that our actual cash burn rate may not be consistent with our expectations; that BioCryst may not have sufficient cash to continue funding the development, manufacturing, marketing or distribution of its products and that additional funding, if necessary, may not be available at all or on terms acceptable to BioCryst. 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, most recent Registration Statement on Form S-3 (filed November 28, 2008), 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 our projections and forward-looking statements.

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