



## Emergency Use Authorization Granted For BioCryst's Peramivir

BIRMINGHAM, Ala., Oct 23, 2009 /PRNewswire-FirstCall via COMTEX News Network/ -- BioCryst Pharmaceuticals, Inc. (Nasdaq: BCRX) today announced that the U.S. Food and Drug Administration (FDA), in response to a request from the U.S. Centers for Disease Control and Prevention (CDC), has issued an emergency use authorization (EUA) for the investigational anti-viral drug intravenous (i.v.) peramivir in certain adult and pediatric patients with confirmed or suspected 2009 H1N1 influenza infection who are admitted to a hospital.

Specifically, i.v. peramivir is authorized only for hospitalized adult and pediatric patients for whom therapy with an i.v. drug is clinically appropriate, based on one or more of the following reasons:

1. the patient is not responding to either oral or inhaled anti-viral therapy, or
2. when drug delivery by a route other than an intravenous route -- e.g., enteral (absorbed by the intestines) or inhaled -- is not expected to be dependable or feasible;
3. for adults only, when the clinician judges i.v. therapy is appropriate due to other circumstances.

Additional information regarding the peramivir EUA is available on the Web at:

[www.cdc.gov/h1n1/eua](http://www.cdc.gov/h1n1/eua)

In advance of any U.S. Government order that may come from the ongoing request for proposal (RFP) negotiations, BioCryst has donated and transferred to the Department of Health and Human Services (HHS) an initial supply sufficient for 1,200 courses of i.v. peramivir 600 mg once-daily for five days. This transfer was made under the development contract with HHS to allow doctors and patients near-term access to the drug, and is separate from the RFP process.

"The issuance of this EUA is important because it makes peramivir a treatment option for physicians in the U.S. during the ongoing influenza health emergency," said Jon P. Stonehouse, Chief Executive Officer at BioCryst. "BioCryst has worked with HHS to enable the Government to rapidly deploy an initial supply of peramivir, and we are prepared to deliver more."

To prepare for peramivir orders that BioCryst may receive from the U.S. or other governments during this pandemic emergency, BioCryst is completing production of approximately 130,000 courses of i.v. peramivir and is prepared to make more, if required.

### *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 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](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 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 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 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.

BCRXW

SOURCE BioCryst Pharmaceuticals, Inc.

<http://www.biocryst.com>

Copyright (C) 2009 PR Newswire. All rights reserved