



## **BIOCRYST REPORTS PRELIMINARY RESULTS FROM A PHASE II CLINICAL TRIAL OF PERAMIVIR IN SUBJECTS WITH ACUTE INFLUENZA**

**Birmingham, Alabama - September 19, 2007** - BioCryst Pharmaceuticals, Inc. (Nasdaq: BCRX) today announced preliminary findings from a Phase II study with intramuscular (i.m.) injection of peramivir, the Company's product candidate for the treatment of seasonal and life-threatening influenza.

The study was a randomized, double-blind, placebo-controlled clinical trial designed to test whether peramivir, when administered acutely in high doses intramuscularly, could reduce the duration of symptoms during seasonal influenza. 344 patients who had a positive rapid antigen test indicating acute influenza illness were randomized to receive intramuscular injections of either placebo or one of two dose levels of peramivir (150mg and 300mg) as a single dose administered within 48 hours of symptom onset. The primary endpoint of the study was the time to alleviation of symptoms in the patients with confirmed influenza infection (n=313).

While the results indicate that in the evaluable population of 313 subjects, a single dose of peramivir demonstrated a treatment improvement over placebo, the improvement was not statistically significant. With regard to the primary endpoint of median time to alleviation of symptoms, the improvement over placebo was 22.9 hours with the 150mg dose (p=0.284) and 21.1 hours with the 300mg dose (p=0.152). Based on a preliminary review, the Company believes that due to the introduction of a shorter injection needle in the Phase II trial compared to the Phase I trial, only one-third of subjects received an adequate intramuscular injection.

In a post hoc analysis, 101 subjects showed evidence of adequate intramuscular injections as measured by a standard laboratory test, serum creatine kinase elevations over baseline. In this group of subjects, peramivir showed a larger treatment effect on the time to alleviation of symptoms. For these 101 subjects, peramivir showed an improvement of 64.8 hours over placebo at the 300mg dose, and an improvement of 44.6 hours over placebo at the 150mg dose. These differences were shown using the same measure of symptom alleviation as used for the primary endpoint, and they indicate a dose response in this group of patients.

At both doses studied, peramivir demonstrated a safety and tolerability profile similar to placebo, both in the total population and in the population showing evidence of intramuscular delivery.

"We are clearly disappointed that we did not achieve the primary endpoint across the entire study population. However, the goal of this Phase II study was to explore the efficacy of peramivir and establish its safety profile in subjects with acute influenza infections as we plan for the phase III trial. In subjects that we believe received the intended dosing of peramivir, we saw patients achieve symptom relief up to 2.6 days faster than placebo, a result that exceeded our expectations. In addition, peramivir demonstrated a safety profile similar to placebo," said Jon P. Stonehouse, President and CEO of BioCryst Pharmaceuticals, Inc. "Based on these results, we have a clear and concise plan to correct the issues identified in this study and continue our preparations to initiate our Phase III program by year end."

BioCryst will sponsor a conference call at 5:00 p.m. Eastern U.S. Time today, Wednesday, September 19, 2007 to discuss today's news in more detail. This call is open to the public and can be accessed live either over the Internet from the company's website [www.biocryst.com](http://www.biocryst.com) or by dialing 1-800-860-2442 (U.S.) or 1-412-858-4600 (international). No passcode is needed for the call.

BioCryst is also currently conducting a Phase II clinical trial studying an intravenous formulation of peramivir in hospitalized patients. That trial is designed to compare the efficacy and safety of intravenous peramivir to orally administered oseltamivir in patients who require hospitalization due to acute influenza.

BioCryst is developing peramivir injection for the treatment of acute influenza, including infection caused by highly virulent, life-threatening strains of influenza. In January, 2006 BioCryst received FDA Fast Track designation for the development of peramivir injection for this indication.

BioCryst is advancing the clinical development of peramivir under terms of a contract from the U.S. Department of Health and Human Services (DHHS) which on January 3, 2007 awarded BioCryst a \$102.6 million, four-year contract to develop peramivir for the treatment of seasonal and life-threatening influenza. Funding from the contract will support Phase II and Phase III product development activities including manufacturing of clinical lots, process validation, clinical studies and other product approval requirements needed for U.S. licensure. BioCryst has retained all of its development and commercialization rights to

peramivir worldwide except for in Japan and Korea where BioCryst recently established strategic partnerships with Shionogi & Co. in Japan, and Green Cross in Korea.

## **About Peramivir**

Peramivir is a member of the class of antiviral agents that inhibit influenza viral neuraminidase, an enzyme that is essential for the spread of influenza virus within the host. Peramivir is an inhibitor of influenza A and B neuraminidases and certain strains of influenza viruses that may be resistant to available neuraminidase inhibitors but are susceptible to peramivir in laboratory tests. Peramivir injection has received Fast Track designation from US FDA and the availability of an intravenous neuraminidase inhibitor may be important in treating patients hospitalized with severe and potentially life-threatening influenza. The availability of an injectable formulation of peramivir could ensure appropriate dosing which may be a concern with currently available oral or inhaled anti-influenza agents.

## **About Influenza**

The influenza virus causes an acute viral disease of the respiratory tract. Unlike the common cold and some other respiratory infections, seasonal flu can cause severe illness, resulting in life-threatening complications. According to the Centers for Disease Control and Prevention, every year in the United States more than 200,000 people are hospitalized due to influenza or its complications, and of this number about 36,000 people die each year. Most at risk are young children, the elderly, and people with seriously compromised immune systems.

Avian influenza A viruses of H5N1 subtype are circulating among birds worldwide. The virus is considered extremely contagious in fowl. It is believed that all species of birds are susceptible to avian influenza, but domestic poultry, including chickens and turkeys, are among the more susceptible to the highly pathogenic strain. According to the World Health Organization, as of September 2007 at least 328 people have been infected with H5N1 avian influenza, of which at least 200 have died. Almost all of these infections are believed to have resulted from contact with infected poultry.

## **About BioCryst**

BioCryst Pharmaceuticals, Inc. is a leader in the use of crystallography and structure-based drug design for the development of novel therapeutics to treat cancer, cardiovascular diseases, autoimmune diseases, and viral infections. The company is advancing multiple internal programs toward potential commercialization including Fodosine™ in oncology, BCX-4208 in transplantation and autoimmune diseases and peramivir in seasonal and life-threatening influenza. BioCryst has a worldwide partnership with Roche for the development and commercialization of BCX-4208, and is collaborating with Mundipharma for the development and commercialization of Fodosine™ in markets across Europe, Asia, Australia and certain neighboring countries. In January, 2007 the U.S. Department of Health and Human Services (DHHS) awarded a \$102.6 million, four-year contract to BioCryst for advanced development of peramivir to treat seasonal and life-threatening influenza. In February 2007 BioCryst established a partnership with Shionogi & Co., to develop and commercialize peramivir in Japan. For more information about BioCryst, please visit the company's web site at <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 our belief that many subjects in the Phase II clinical trials of peramivir did not receive adequate dosing by i.m. injection may not be correct, that final results and analysis of the peramivir Phase II trial may differ from the preliminary results and analysis, that DHHS and the FDA may not agree with our analysis, that DHHS may further condition, reduce or eliminate future funding of the peramivir program, that we may not commence in timely fashion or at all the planned Phase III trial for peramivir and if commenced, it may not be successful, that the Phase II trial of BCX-4208 for psoriasis may not be successfully completed, that development and commercialization of Fodosine™ in both ALL and CTCL may not be successful, that we may not resolve satisfactorily the particulate matter issue with the intravenous formulation of Fodosine™, that DHHS could reduce or eliminate funding for peramivir, that we or our licensees may not be able to enroll the required number of subjects in planned clinical trials of our product candidates and that such clinical trials may not be successfully completed, 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 clinical trials may not have positive results, that we may not be able to complete successfully the Phase IIb trials for Fodosine™ that are currently planned to be pivotal, that we may not be able to announce preclinical developments for additional compounds by year-end 2007 as currently proposed, that we or our licensees may not be able to continue future development of our current and future development programs, that our development programs may never result in future product, license or royalty payments being received by BioCryst, that BioCryst may not reach favorable agreements with potential pharmaceutical

and biotech partners for further development of its product candidates, 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 (File No. 333-145638), Quarterly Reports on Form 10-Q, current reports on Form 8-K which identify important factors that could cause the actual results to differ materially from those contained in the projections or forward-looking statements.

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