



## **BIOCRYST INITIATES PHASE II CLINICAL TRIAL TO EVALUATE INTRAVENOUS PERAMIVIR IN PATIENTS HOSPITALIZED WITH INFLUENZA**

**Birmingham, Alabama – July 24, 2007** –BioCryst Pharmaceuticals, Inc. (Nasdaq: BCRX) today announced the initiation of a Phase II clinical trial in hospitalized patients using an intravenous (i.v.) formulation of peramivir, the company's lead influenza neuraminidase inhibitor. The trial will compare the efficacy and safety of intravenous peramivir to orally administered oseltamivir in patients who require hospitalization due to acute influenza.

"We are pleased to initiate this Phase II trial and we firmly believe that the availability of an intravenous formulation of peramivir will significantly improve options for treatment of persons with serious illness due to influenza and be a meaningful addition into the influenza market," said Jon P. Stonehouse, President and Chief Executive Officer of BioCryst. "The Centers for Disease Control estimates that over 200,000 persons are hospitalized and 36,000 persons die each year in the United States due to influenza and its complications. There is currently no drug for influenza that is available as an injection for hospital use and this intravenous formulation of peramivir holds particular promise in this indication."

The multicenter, randomized, double-blind study will compare the efficacy and safety of peramivir administered intravenously once daily for five days versus oral oseltamivir administered twice daily for five days in adults who are hospitalized with acute influenza. The current study will be conducted by investigators in both the Northern and Southern Hemispheres during the present and upcoming influenza seasons with enrollment expected in the US, Canada, Hong Kong, Singapore, Australia, New Zealand, and South Africa.

In addition to the trial announced today, BioCryst is currently conducting a separate Phase II trial using an intramuscular (i.m.) formulation of peramivir in individuals with influenza in the outpatient setting. Both studies are based on the positive Phase I clinical data obtained in 2006 and reported at the 46th Annual ICAAC meeting in September, 2006.

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. At the 46th Annual Interscience Conference on Antimicrobial Agents and Chemotherapy in September, 2006, data were presented showing that injectable formulations of peramivir were safely administered to healthy subjects at daily doses up to approximately 600 mg. At the same meeting, animal data were presented showing peramivir promoted survival in animals infected with highly pathogenic strains of the H5N1 virus. 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 from flu complications, and about 36,000 people die from flu. 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, at least

318 people have contracted H5N1 avian influenza, of which at least 192 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 the Phase II clinical trials of peramivir 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 commence the proposed Phase III trial for peramivir within the time frame we currently expect or at all, 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, 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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