



## **EMEA GRANTS ORPHAN DRUG DESIGNATION TO BIOCRYST'S FODOSINE™ FOR THE TREATMENT OF CUTANEOUS T-CELL LYMPHOMA (CTCL)**

Birmingham, Alabama – February 6, 2007 - BioCryst Pharmaceuticals, Inc. (Nasdaq: BCRX) today announced that Fodosine™ has been granted orphan status for the treatment of cutaneous T-cell lymphoma (CTCL), by the Committee for Orphan Medicinal Products (COMP) of the European Medicines Agency (EMA).

This is the second indication for which the EMA has granted orphan drug status to Fodosine™ following regulatory submissions by Mundipharma, BioCryst's European Fodosine™ partner. In November 2006, the EMA granted orphan drug designation to Fodosine™ for the treatment of T-cell acute lymphoblastic leukemia (ALL).

Fodosine™, BioCryst's lead oncology candidate is currently being studied in clinical trials for indications including T-cell acute lymphoblastic leukemia (T-ALL), cutaneous T-cell lymphoma (CTCL), B-cell acute lymphoblastic leukemia (B-ALL) and chronic lymphocytic leukemia (CLL). In January 2007, BioCryst initiated a pivotal phase IIb clinical trial with Fodosine™, in the treatment of patients with relapsed or refractory T-cell leukemia/lymphoma.

The EMA's "Orphan Medicinal Product Designation" is designed to promote the development of drugs which may provide "significant benefit" to patients suffering from rare diseases identified as "life-threatening or very serious." Under EMA guidelines, Orphan Medicinal Product Designation provides 10 years of potential market exclusivity if the product candidate is approved for marketing in the European Union. Orphan status also permits EMA assistance in optimizing the candidate's clinical development through participation in designing the clinical protocol and preparing the marketing application. Additionally, a drug candidate designated by the EMA as an Orphan Medicinal Product may qualify for a reduction in regulatory fees as well as a European Union-funded research grant.

"The EMA's decision to grant Fodosine™ orphan drug designation for the treatment of patients with CTCL signifies another important step for BioCryst and Mundipharma in our development of Fodosine™," said Jon P. Stonehouse, CEO of BioCryst. "This action by the EMA reinforces our belief that Fodosine™ has worldwide potential to become an important treatment alternative for patients with this debilitating disease."

In 2005, the United States Food and Drug Administration (FDA) granted Orphan Drug designation to Fodosine™ for three indications: T-cell non-Hodgkin's lymphoma, including CTCL; CLL and related leukemias including T-cell prolymphocytic leukemia, adult T-cell leukemia, and hairy cell leukemia; and for the treatment of B-ALL. Additionally the FDA has granted "fast track" status to the development of Fodosine™ for the treatment of relapsed or refractory T-cell leukemia.

### **About Fodosine™**

Fodosine™ is a transition-state analog inhibitor of the target enzyme purine nucleoside phosphorylase (PNP). The drug is currently being studied in clinical trials for indications including T-cell acute lymphoblastic leukemia (T-ALL), cutaneous T-cell lymphoma (CTCL), B-cell acute lymphoblastic leukemia (B-ALL) and chronic lymphocytic leukemia (CLL).

In early 2006, BioCryst entered into a strategic collaboration with Mundipharma International Holdings Limited to develop and commercialize Fodosine™ in markets across Europe, Asia, Australia and certain neighboring countries for use in oncology.

### **About Mundipharma**

Mundipharma is one of the Purdue/Mundipharma/Napp independent associated companies - privately owned companies and joint ventures covering the world's pharmaceutical markets. The companies worldwide are dedicated to bringing to patients with severe and debilitating diseases the benefits of novel treatment options in fields such as severe pain, haemato-oncology and respiratory disease. For more information: [www.mundipharma.co.uk](http://www.mundipharma.co.uk)

### **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 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. For more information about BioCryst, please visit the company's web site at <http://www.biocryst.com>.

### **Forward-looking statements**

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 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 trial for Fodosine™ that is currently planned to be pivotal, 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.

Contact:  
BioCryst Pharmaceuticals, Inc.  
Jonathan M. Nugent  
V.P. Corporate Communications  
(205) 444-4633