



## **BIOCRYST'S FODOSINE™ GRANTED ORPHAN STATUS IN EUROPE**

### **EUROPEAN MEDICINES AGENCY (EMA) GRANTS ORPHAN MEDICINAL PRODUCT DESIGNATION TO BIOCRYST'S LEAD ONCOLOGY CANDIDATE, FODOSINE™, FOR TREATMENT OF T-CELL ACUTE LYMPHOBLASTIC LEUKEMIA (T-CELL ALL)**

Birmingham, Alabama: November 20, 2006 - BioCryst Pharmaceuticals, Inc. (Nasdaq: BCRX) today announced that following the favorable opinion of the European Committee for Orphan Medicinal Products (COMP), the European Medicines Agency (EMA) has granted an "Orphan Medicinal Product Designation" for the anticancer drug Fodosine™ for the treatment of T-Cell Acute Lymphoblastic Leukemia (T-Cell ALL).

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 Status is an important milestone as we continue to make significant strides to develop and commercialize Fodosine™ in North America and in close collaboration with our partner in Europe, Mundipharma, simultaneously advance Fodosine™ toward commercialization in Europe," said Charles E. Bugg, Ph.D., Chairman and CEO of BioCryst. "We are gratified by this decision which should accelerate the path to potential marketing approval for Fodosine™ in Europe."

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.

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 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 leukemia (T-ALL), cutaneous T-cell lymphoma (CTCL), B-cell acute lymphoblastic leukemia (B-ALL) and chronic lymphocytic leukemia (CLL). BioCryst is in the process of initiating a Phase IIb pivotal clinical trial of Fodosine™ in the treatment of patients who have failed two or more previous therapies for T-cell leukemia.

#### **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-208 in transplantation and autoimmune diseases, peramivir in seasonal and life-threatening influenza, and BCX-4678 in hepatitis C. BioCryst has a worldwide partnership with Roche for the development and commercialization of BCX-4208 and is collaborating with Mundipharma Holdings for the development and commercialization of Fodosine™ in markets across Europe, Asia, Australia and certain neighboring countries. 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 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 or foreign regulatory authorities, 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™ pursuant to the Special Protocol Assessment letter 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 or governmental agencies 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, and the risks, uncertainties and factors identified in the documents BioCryst files periodically with the Securities and Exchange Commission, specifically including BioCryst's most recent Annual Report on Form 10-K, Quarterly Reports on Form 10-Q, current reports on Form 8-K. These statements reflect our current views with respect to future events and BioCryst has no obligation to update or revise the statements. BioCryst cautions that you should not place undue reliance on these forward-looking statements.

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