



## **BIOCRYST PHARMACEUTICALS INITIATES ORAL PHASE I CLINICAL TRIAL IN CUTANEOUS T-CELL LYMPHOMA**

### **- Trial Initiates Development of Oral Forodesine Hydrochloride -**

Birmingham, Alabama -October 19, 2004 - BioCryst Pharmaceuticals, Inc. (Nasdaq NM: BCRX) announced today that the first patient has been dosed in a Phase I trial of oral forodesine hydrochloride, its lead anti-cancer compound formerly known as BCX-1777, in refractory patients with cutaneous T-cell lymphoma (CTCL). Forodesine hydrochloride is a purine nucleoside phosphorylase (PNP) inhibitor, which functions by blocking the T-cell's DNA synthesis machinery. The small molecule drug is being developed for treatment of T-cell mediated cancers, and has been designated an "Orphan Drug" for three general indications, including patients with CTCL. BioCryst completed a Phase I trial with intravenous forodesine hydrochloride in CTCL patients during the second quarter of 2004, and filed an IND for the oral formulation of forodesine hydrochloride with the U.S. Food and Drug Administration (FDA) in early July.

This Phase I, open label trial is the first to administer capsules of forodesine hydrochloride, and will study the pharmacokinetic effects of the drug at 40, 80, and 160 mg/m<sup>2</sup> levels. A minimum of 3 patients at each dose level will be enrolled, with a regimen of four weeks during which the patients will receive once daily oral doses of forodesine hydrochloride. The trial will include CTCL patients with earlier stages of disease than the advanced stage patients included in BioCryst's Phase I intravenous forodesine hydrochloride trial. Assuming results are positive, BioCryst plans to use the results of this trial to design a Phase II trial with oral forodesine hydrochloride in CTCL patients for initiation in early 2005.

"The initiation of this oral Phase I trial marks the continued growth of our forodesine hydrochloride clinical trial program," stated Dr. Charles E. Bugg, Chairman and CEO of BioCryst. "CTCL is the most common form of T-cell cancer. We believe oral forodesine hydrochloride has the potential to be an effective therapy for this and other T-cell cancers and potentially offers a dramatic improvement in both dose administration and patient quality of life."

"As our investigation of forodesine hydrochloride expands to additional cancer indications, the oral formulation will be a definite advantage, particularly for extended treatment of diseases such as CTCL, where patients generally have slowly progressing disease and are almost always treated as outpatients," commented Dr. J. Claude Bennett, President, Chief Operating Officer and Medical Director of BioCryst. "We are optimistic that the patient-friendly, once-daily oral dosing regimen will attract rapid patient enrollment in this CTCL trial as well as our planned future trials."

### **About BioCryst**

BioCryst Pharmaceuticals, Inc. designs, optimizes and develops novel drugs that block key enzymes involved in cancer, cardiovascular and autoimmune diseases, and viral infections. BioCryst integrates the necessary disciplines of biology, crystallography, medicinal chemistry and computer modeling to effectively use structure-based drug design to discover and develop small molecule pharmaceuticals.

BioCryst's lead product candidate, forodesine hydrochloride, formerly known as BCX-1777, an inhibitor of purine nucleoside phosphorylase (PNP), is currently in a Phase IIa trial for patients with T-cell malignancies and a Phase I trial with oral forodesine hydrochloride in CTCL. In addition, BioCryst plans to initiate a Phase I/II trial for B-cell acute lymphoblastic leukemia during 2004. Forodesine hydrochloride has been granted 'Orphan Drug' status by the U.S. Food and Drug Administration for three indications: T-cell non-Hodgkin's lymphoma, including cutaneous T-cell lymphoma; chronic lymphocytic leukemia (CLL) and related leukemias including prolymphocytic leukemia, adult T-cell leukemia, and hairy cell leukemia; and for treatment of acute lymphoblastic leukemia (ALL).

BioCryst also plans to initiate a Phase I study with a second generation PNP inhibitor, BCX-4208, during 2004 for use in autoimmune diseases such as psoriasis. In addition, BioCryst has several new enzyme targets in drug discovery including tissue factor/factor VIIa and hepatitis C polymerase. For more information about BioCryst, please visit the company's web site at [www.biocryst.com](http://www.biocryst.com).

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 may not be able to enroll the required number of subjects in clinical trials of forodesine hydrochloride, that the Phase I trial of forodesine hydrochloride for treatment of patients with cutaneous T-cell lymphoma may not be successfully completed, that BioCryst may not commence as expected additional trials with forodesine hydrochloride and Phase I studies with BCX-4208, that forodesine hydrochloride, BCX-4208, or any of our other product candidates may not receive required regulatory clearances from the FDA, that Phase IIa clinical trials of forodesine hydrochloride may not show the drug is effective over the 6-week period, that we may not be able to obtain a Special Protocol Assessment or otherwise be able to complete successfully the Phase IIb trial that is currently planned, that we may not be able to continue future development of forodesine hydrochloride, BCX-4208 or any of our other current development programs including tissue factor/factor VIIa and hepatitis C polymerase, that forodesine hydrochloride, BCX-4208 or our other development programs may never result in future product, license or royalty payments being received by BioCryst, 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 and Quarterly Reports on Form 10-Q, 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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