



## **BIOCRYST ANNOUNCES PRESENTATION AND UPDATE OF RESULTS WITH INTRAVENOUS FORODESINE HYDROCHLORIDE IN PATIENTS WITH CUTANEOUS T-CELL LYMPHOMA, B-CELL ACUTE LYMPHOBLASTIC LEUKEMIA (ALL) AND T-CELL ALL AT THE AMERICAN SOCIETY OF HEMATOLOGY (ASH)**

Birmingham, AL - December 6, 2004 - BioCryst Pharmaceuticals, Inc. (Nasdaq: BCRX) today announced that two presentations on the clinical development of forodesine hydrochloride, its lead product candidate for the treatment of certain leukemias and lymphomas, were given at the American Society of Hematology (ASH) Annual Meeting, which is being held December 4-7, 2004, in San Diego.

Abstracts covering these presentations, which were prepared by clinical investigators and BioCryst staff, are available on the ASH website, [www.hematology.org](http://www.hematology.org), and were published in the journal *Blood*, Volume 103, issue 12, which is available online at <http://www.bloodjournal.org>.

Dr. Richard R. Furman of Cornell University Weill Medical College is currently presenting a study entitled, "Intravenous Forodesine (BCX-1777), a Novel Purine Nucleoside Phosphorylase (PNP) Inhibitor, Demonstrates Clinical Activity in Phase I/II Studies in Patients with B-cell Acute Lymphoblastic Leukemia" (R. Furman et al.), during today's Poster Session at 5:30 p.m. (PT). This phase I/II multi-center dose-escalation study evaluated forodesine HCl in 15 patients with various hematological malignancies, six of whom had B-cell acute lymphoblastic leukemia (B-ALL). The drug, administered once a day for five days, was well-tolerated in all patients, at all dose levels. Seven of the fifteen patients treated (2 T-cell malignancies and 5 B-ALL) including five of the six treated B-ALL patients, demonstrated a hematological benefit, defined as a decrease in tumor burden. Two patients also showed normalization of bone marrow precursor elements.

The study concludes that forodesine HCl could represent an important breakthrough in the development of a more effective and less toxic treatment for ALL. Based on the encouraging clinical activity seen in this trial, BioCryst will initiate a phase II trial in B-ALL, scheduled to begin during the fourth quarter of 2004.

Dr. Furman's presentation also included new data from BioCryst's on-going Phase IIa multi-center trial of intravenous forodesine HCl, a six week course of therapy, in relapsed or refractory T-cell leukemia patients. To date, the trial has enrolled seven patients, and three have completed treatment. Four patients have shown a striking hematological improvement including one complete response. All four of these patients have shown striking elevations of plasma dGuo, demonstrating effective inhibition of PNP.

A second abstract, "Intravenous Forodesine (BCX-1777), a Novel Purine Nucleoside Phosphorylase (PNP) Inhibitor, Demonstrates Clinical Activity in Patients with Refractory Cutaneous T-cell Lymphoma" (M. Duvic et al.), was presented by Dr. Madeleine Duvic of the M.D. Anderson Cancer Center during the Poster Session on Sunday, December 5 at 6:00 p.m. (PT). Results from the multi-center dose-escalating Phase I CTCL trial, which treated 13 patients with intravenous forodesine hydrochloride, demonstrated that nine out of 13 patients showed improvement in skin and/or a pharmacodynamic response as measured by a decrease in the absolute Sezary cell numbers and/or the CD4/CD8 ratio. Three complete responses and one partial response were observed. Near-total inhibition of PNP was observed at a dose of 40 mg/m<sup>2</sup>. Five patients in this study were approved by the FDA for compassionate use. Two patients who received forodesine HCl on compassionate use continued to show evidence of clinical activity over a period of 9 -11 months.

Based on these results, BioCryst initiated a Phase I trial in CTCL patients using an oral formulation of forodesine HCl, during October 2004, to determine pharmacokinetic equivalents of this formulation at 40, 80 and 160 mg/m<sup>2</sup> per day, relative to the previously administered IV drug.

### **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 the fourth quarter 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's second-generation PNP inhibitor, BCX-4208 is currently in a Phase I study of healthy volunteers with the goal of initiating a Phase II study during 2005 in patients with psoriasis. In addition, BioCryst has other 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 or BCX-4208, that each of the Phase IIa trial for patients with T-cell malignancies, Phase I trial of BCX-4208 and 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 II 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 ongoing and future clinical trials will have positive results, 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, Quarterly Reports on Form 10-Q, and 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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