BioCryst Pharmaceuticals Continues Forodesine HCl Program in Chronic Lymphocytic Leukemia

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BioCryst Pharmaceuticals (Nasdaq: BCRX) today announced interim data from the ongoing Forodesine HCl Phase 2 program in patients with chronic lymphocytic leukemia (CLL) and data from a healthy subject pharmacokinetic and pharmacodynamic study. The CLL study will continue with an amendment to study a new dosing regimen of oral Forodesine, 200 mg twice-daily.

An interim analysis was conducted on data from an exploratory Phase 2 single-arm, open-label program in patients with CLL whose previous treatment had failed. While this analysis showed that no partial or complete responses were observed, five out of 13 patients administered 200 mg of Forodesine HCl once-daily had substantial reductions in malignant lymphocytes, and at the time of the analysis, seven patients were still on study. Forodesine HCl was generally safe and well-tolerated at the 200 mg once-daily dose.

In a parallel, healthy subject, pharmacokinetic and pharmacodynamic study, BioCryst compared the effect of seven days of 200 mg Forodesine HCl dosed once-daily with seven days of 200 mg Forodesine HCl dosed twice-daily. The study demonstrated substantially increased drug exposure and pharmacodynamic effect in subjects administered Forodesine HCl 200 mg twice-daily. Drug exposure, as measured by AUC, increased by 63 percent ($P<0.001$) for twice-daily dosing compared to once-daily dosing. Serum uric acid levels were reduced at steady state compared to baseline by 50.0 percent for twice-daily dosing compared to 23.5 percent for once-daily dosing ($p<0.001$), indicating increased PNP enzyme inhibition with twice-daily dosing.

"The interim data demonstrates that Forodesine HCl has potential activity in patients with CLL," stated Dr. William Sheridan, BioCryst's Chief Medical Officer. "Based on these results and the normal subject pharmacokinetic and pharmacodynamic study results, we have amended the ongoing Phase 2 study, and will now administer Forodesine HCl twice-daily to examine the potential benefits of increased drug exposure. We expect to provide an update on this trial by the end of 2009."

"In our experience to date, Forodesine HCl was very well tolerated by patients in this Phase 2 study. We are pleased with these results and look forward to further testing to determine the efficacy of Forodesine HCl when administered twice-daily in patients with CLL," stated Dr. Asher Chanan-Khan, Associate Professor of Oncology at Roswell Park.

About CLL

CLL is a disease characterized by high numbers of circulating abnormal lymphocytes (B-cells) in the peripheral blood. The disease often involves enlargement of lymph nodes in various parts of the body as well as enlargement of the spleen. CLL is the most common adult leukemia, with over 15,000 new cases per year in the United States and more than 4,000 deaths. It typically occurs in individuals between 65 and 70 years of age.

CLL is not a rapidly growing cancer, but the abnormal cells accumulate in the blood, bone marrow, lymph nodes, and spleen, resulting in enlargement of these organs and decreased bone marrow and immune function. This disease interferes with the normal production of antibodies and immunoglobulins, so the body cannot properly fight infections. While therapy has improved, CLL remains incurable and patients often suffer significant infections as a consequence of the disease and treatment.

About Forodesine HCl

Forodesine HCl 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) and chronic lymphocytic leukemia (CLL).

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

About BioCryst

BioCryst is an integrated biopharmaceutical company utilizing crystallography and structure-based drug design to develop a

deep pipeline of novel therapeutics targeting major illnesses. BioCryst is currently advancing investigational new drugs discovered in-house in late-stage clinical trials for influenza and lymphoma. In addition, the Company has a pre-clinical portfolio of novel compounds, directed against infectious, cardiovascular, and autoimmune disease targets, to create long-term sustainable value. The Company's strategic alliances with the U.S. Department of Health and Human Services, Shionogi & Co., Ltd., Green Cross Corporation and Mundipharma International Holdings Ltd. validate its scientific foundation and the utility of its product candidates. For more information, please visit the Company's Web site at 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 our belief that many subjects in the Phase 2 clinical trials of peramivir did not receive adequate dosing by intramuscular injection may not be correct, that HHS and the Food & Drug Administration (FDA) may not agree with our analysis, that HHS may further condition, reduce or eliminate future funding of the peramivir program, that ongoing peramivir clinical trials may not be successful, that the peramivir program may not be successful, that the pivotal trial with forodesine HCl in cutaneous T-cell lymphoma (CTCL) may not meet its endpoint, that development and commercialization of forodesine HCl in CTCL may not be successful, 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 preclinical and clinical development may not have positive results, 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 be able to retain its current pharmaceutical and biotechnology partners for further development of its product candidates or it may not reach favorable agreements with potential pharmaceutical and biotechnology partners for further development of its product candidates, that our projected burn rate may not be consistent with our expectations, 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, most recent Registration Statement on Form S-3 (filed November 28, 2008), 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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