BioCryst Pharmaceuticals Announces Presentation of Forodesine Data at the 45th Annual Meeting of the American Society of Clinical Oncology

BIRMINGHAM, Ala., May 14, 2009 /PRNewswire-FirstCall via COMTEX News Network/ -- BioCryst Pharmaceuticals (Nasdaq: BCRX) today announced long-term data from a Phase 2 study of forodesine, the Company's lead oncology compound, in patients with cutaneous T-cell lymphoma (CTCL). The data will be presented at the 45th Annual Meeting of the American Society of Clinical Oncology (ASCO) being held in Orlando, Florida from May 29-June 2. Forodesine is a transition-state analog inhibitor of purine nucleoside phosphorylase (PNP), a purine salvage pathway enzyme that is essential for the proliferation of T-cells and B-cells.

The poster entitled "Long-Term Treatment of CTCL with the Oral PNP Inhibitor, Forodesine" (Abstract #8552, M. Duvic et. al.) will be in a general ASCO poster session on Saturday, May 30 from 8:00 a.m. to 12:00 p.m. Eastern Time on Level 2, West Hall C, Board Q18 of the Orlando Convention Center.

The open-label, dose escalation study evaluated 40-320 mg/m2 of forodesine given once-daily for four weeks to determine the maximum tolerated dose and optimal biologic dose (OBD). The OBD was determined to be 80 mg/m2 of forodesine. Additional patients were enrolled in this trial to further assess the long-term safety and clinical efficacy at the 80 mg/m2 dose level. The primary efficacy endpoint was objective response rate, defined as greater than or equal to a 50 percent improvement by a severity-weighted assessment tool.

The overall response rate in the intent to treat population was 17 of 64 patients (27 percent), including 14 of 36 patients (39 percent) treated with the 80 mg/m2 dose. As of October 2008, nine of 64 patients (14 percent) received forodesine treatment for greater than 12 months. Of these nine patients, six discontinued treatment. Four patients discontinued treatment because of progressive disease, one withdrew consent and one discontinued due to an adverse event (diffuse large b-cell lymphoma). The median time on treatment for these six patients was 440 days. Through October 1, 2008, the other three patients remained on therapy for 416, 710 and 863 days, respectively.

"This Phase 2 trial further shows the safety and efficacy of an oral PNP inhibitor, forodesine, for CTCL patients of all stages who have failed standard therapies," said Madeleine Duvic, M.D., Professor of Medicine and Dermatology, Deputy Chairman, Department of Dermatology at the MD Anderson Cancer Center.

"We believe these data further support the clinical utility of forodesine as a treatment for CTCL and are encouraged by its safety and efficacy profile in this study," said Dr. William P. Sheridan, BioCryst's Chief Medical Officer. "We continue to actively enroll patients in our pivotal Phase 2 study of forodesine in patients with CTCL and look forward to results from this study in the first half of next year."

Of the nine patients that received forodesine treatment for 12 or more months, the most frequent adverse events were nausea (44 percent), fatigue (22 percent), peripheral edema (22 percent), dyspnea (22 percent) and urinary casts (22 percent). Grade 3 or higher adverse events were diffuse large B-cell lymphoma and peripheral edema. There were no hematologic or infection adverse events related to forodesine. Grade 3 lymphopenia and a CD4 count of less than 200 were noted in eight of the nine subjects and four of the nine subjects, respectively.

About BioCryst

BioCryst is a biopharmaceutical company that has developed a deep pipeline of novel therapeutics targeting major illnesses by employing crystallography and structure-based drug design. 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 the pivotal trial with forodesine in cutaneous T-cell lymphoma (CTCL) may not meet its endpoint; that development and commercialization of forodesine 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 actual 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, and current reports on Form 8-K, all of which identify important factors that could cause the actual results to differ materially from those contained in our projections and forward-looking statements.

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