Data from Phase 2 Study of Peramivir in Patients Hospitalized with Influenza Presented at the XI International Symposium on Respiratory Viral Infections

BIRMINGHAM, Ala., Feb 23, 2009 /PRNewswire-FirstCall via COMTEX News Network/ -- BioCryst Pharmaceuticals (Nasdaq: BCRX) today announced that the full data set from an exploratory Phase 2 study of peramivir in patients hospitalized for influenza was presented by the study's Principal Investigator, Dr. Michael G. Ison, Assistant Professor, Divisions of Infectious Diseases and Organ Transplantation at Northwestern University Feinberg School of Medicine, during the XI International Symposium on Respiratory Viral Infections taking place in Bangkok, Thailand, February 19 through February 22, 2009. This exploratory Phase 2 trial compared the efficacy and safety of five days of therapy with either 200 mg intravenous (i.v.) peramivir per day, 400 mg i.v. peramivir per day or 75 mg oral oseltamivir twice-a-day, in patients who required hospitalization related to influenza.

The primary objective of the study was to evaluate time to clinical stability, which is a composite endpoint comprised of normalization of temperature, oxygen saturation, respiratory rate, systolic blood pressure and heart rate. This type of endpoint has previously been used in pneumonia studies, but not in influenza. Secondary objectives of the study included evaluation of viral shedding, mortality, clinical relapse and time to resumption of usual activities. The primary efficacy population was defined as patients with confirmed influenza.

As reported in October 2008, there were no statistically significant differences in any of the efficacy endpoints between the three treatment arms, and peramivir was generally safe and well-tolerated at these dose levels. Evaluation of time to clinical stability, the primary endpoint, showed a median of 23.7 hours for peramivir 200 mg, 37.0 hours for peramivir 400 mg and 28.1 hours for oseltamivir (p=0.306). This exploratory endpoint was driven by resolution of fever. Viral shedding (time weighted change from baseline in viral titer) was reduced by a median of -2.0 logs for peramivir 200 mg, -2.1 logs for peramivir 400 mg, and -1.9 logs for oseltamivir (p=0.908). There was no mortality in the primary efficacy population, and there were no clinical relapses. Patients were discharged from hospital after a median of 4.0 days for peramivir 200 mg, 3.8 days for peramivir 400 mg, and 4.0 days for oseltamivir (p=0.994). The median number of days required for resumption of usual activities was 8.8 days for peramivir 200 mg, 9.0 days for peramivir 400 mg, and 13.7 days for oseltamivir (p=0.276).

"We are encouraged by these data and are currently working with the U.S. Food and Drug Administration to determine the next steps for peramivir as a treatment for patients hospitalized with influenza," said Dr. William P. Sheridan, BioCryst's Chief Medical Officer. "There are currently no approved treatment options for the 200,000 patients hospitalized for influenza each year and we believe peramivir may be a potential new option for these patients."

"This study greatly enhances our knowledge of the clinical and virologic course of influenza in hospitalized patients who receive neuraminidase inhibitors," stated Dr. Ison. "Peramivir holds promise as a once-daily intravenous treatment that is safe and potentially effective for use in patients with acute influenza, including the elderly and patients with underlying cardiac or pulmonary disease."

The multicenter, randomized, double-blind, double-dummy, active-controlled, Phase 2 study enrolled 137 patients, who tested positive by rapid antigen test (RAT) for influenza and had one or more criteria for hospitalization, namely: age greater than or equal to 60 years, chronic lung disease, congestive heart failure, diabetes mellitus, low oxygen saturation, low blood pressure, or severity of illness requiring supportive care. Of the 137 patients randomized, 122 age 19 to 101 years had influenza confirmed by polymerase chain reaction (PCR) testing and were included in the intent-to-treat infected (ITTI) patient population; 41 patients received oseltamivir 75 mg orally twice-daily, 41 patients received 200 mg i.v. peramivir once-daily and 40 patients received 400 mg i.v. peramivir once-daily. The study was conducted in the United States, Canada, Hong Kong, Singapore, Australia, New Zealand, and South Africa, in 2007 and 2008.

About Peramivir

Peramivir is an antiviral agent that inhibits the interactions of influenza neuraminidase, an enzyme which is critical to the spread of influenza within a host. In laboratory tests, peramivir has shown activity against viral strains that are resistant to currently available treatments and has been safely administered to healthy subjects at high dose levels. Peramivir is currently being studied in hospitalized and outpatient influenza, utilizing either an intramuscular or intravenous formulation. A Phase 2 trial in outpatient influenza is currently ongoing, the Phase 2 trial in hospitalized influenza was completed in 2008, and BioCryst's partner, Shionogi & Co., Ltd. has a pivotal Phase 3 program of peramivir in outpatient influenza underway.

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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