BioCryst Reports Results From the First-Ever Completed Active-Controlled Phase 2 Study in Hospitalized Influenza

Management to Host Conference Call at 8:30 a.m. Eastern Time Today to Discuss Results

BIRMINGHAM, Ala., Oct 27, 2008 /PRNewswire-FirstCall via COMTEX News Network/ -- BioCryst Pharmaceuticals, Inc. (Nasdaq: BCRX) today announced results of an exploratory Phase 2 trial of intravenous (i.v.) peramivir, a neuraminidase inhibitor, in patients hospitalized for acute serious or potentially life-threatening influenza. The Phase 2 trial compared the efficacy and safety of five days of therapy with either 200 mg 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. These results will be submitted to an upcoming medical meeting.

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.

In the primary efficacy population, for all groups combined, the study demonstrated a median of 25.3 hours to clinical stability, a median of 2.0 log reduction in time weighted change from baseline in viral titer, zero mortality, no clinical relapse and a median of 10.8 days of time to resumption of usual activities. There were no statistically significant differences in any of the efficacy endpoints between the three treatment arms. Peramivir was generally safe and well-tolerated at these dose levels.

"This landmark study provides us great insight into the course of treatment for patients who are hospitalized for influenza. The results indicate a potential role for antiviral therapy, which is critical as currently there are no antivirals approved for patients hospitalized for acute serious or potentially life-threatening influenza," said Dr. Michael Ison, Assistant Professor, Divisions of Infectious Diseases and Organ Transplantation at Northwestern University Feinberg School of Medicine and Principal Investigator in the study.

"We are very encouraged by how quickly the virus cleared, how well the patients did overall and the safety profile of peramivir in this study," said Dr. William P. Sheridan, BioCryst's Chief Medical Officer. "According to the U.S. Centers for Disease Control, 36,000 people die of complications from influenza each year. Therefore, the observed zero mortality in patients with confirmed influenza in this study is an important finding."

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.

Health and Human Services Contract

BioCryst is advancing the clinical development of peramivir under terms of a contract from the U.S. Department of Health and Human Services (HHS) which on January 3, 2007 awarded BioCryst a $102.6 million, four-year contract to develop peramivir for the treatment of seasonal and life-threatening influenza. Funding from the contract has supported the Phase 2 development activities of peramivir in outpatient and hospitalized flu, including manufacturing of clinical lots, process validation, clinical studies and other product approval requirements toward U.S. licensure. BioCryst has retained all of its development and commercialization rights to peramivir worldwide except in Japan, Korea and recently Taiwan where BioCryst is in a strategic partnership with Shionogi & Co. Ltd. in Japan and Taiwan, and Green Cross in Korea.

Conference Call and Web cast

BioCryst's management team will host a conference call and Web cast on Monday, October 27 at 8:30 a.m. Eastern Time to

discuss the results further. To participate in the conference call, please dial 1-877-627-6585 (United States) or 1-719-325-4896 (International). No passcode is needed for the call. The Web cast can be accessed by logging onto http://www.biocryst.com. Please connect to the Web site at least 15 minutes prior to the start of the conference call to ensure adequate time for any software download that may be necessary.

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 recently completed and BioCryst's partner, Shionogi & Co., Ltd. is preparing for a pivotal Phase 3 trial of peramivir in outpatient influenza.

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 website 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 II 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 (File No. 333-145638), 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.

BCRXW

SOURCE BioCryst Pharmaceuticals, Inc.

http://www.biocryst.com