BioCryst Reports Positive Preliminary Results of a Shionogi & Co., Ltd. Sponsored Phase II Study of I.V. Peramivir for the Treatment of Influenza in the Outpatient Setting

BIRMINGHAM, Ala., July 28, 2008 /PRNewswire-FirstCall via COMTEX News Network/ -- BioCryst Pharmaceuticals, Inc. (Nasdaq: BCRX) today announced preliminary results of a Phase II study of intravenous (i.v.) peramivir administered via a single dose injection in the outpatient setting for the treatment of seasonal influenza. The trial, conducted by BioCryst's partner, Shionogi & Co., Ltd. in Japan, met its primary endpoint of improvement in the median time to alleviation of symptoms in subjects with confirmed, acute, uncomplicated influenza infection, compared to placebo alone. This result was highly statistically significant. Further, safety assessments confirmed that peramivir was generally well-tolerated. These data will be submitted for presentation at an upcoming medical conference. Based on the study's preliminary results, Shionogi has commenced preparations for a Phase III trial of i.v. peramivir in the outpatient setting.

The Phase II study was a randomized, double-blind, placebo-controlled trial, which enrolled 300 subjects who had a positive rapid antigen test indicating acute influenza illness. Subjects were randomized to receive an i.v. injection of placebo or one of two doses of peramivir (300 mg and 600 mg) as a single dose administered within 48 hours of symptom onset.

"The Shionogi study supports clinical efficacy for i.v. peramivir in the treatment of seasonal influenza," commented Rich Whitley, M.D., Professor in the Department of Pediatrics at the University of Alabama at Birmingham. "These data allow us to optimistically anticipate the impact peramivir may have as a potential treatment for influenza in this setting. With the advent of influenza virus resistant to currently approved neuraminidase inhibitors, new therapeutic options such as peramivir are necessary."

Dr. Thomas J. Simon, BioCryst's Senior Medical Advisor, stated, "Peramivir has now been studied in over 550 patients, allowing us to develop an extensive library of clinical knowledge about this potential therapy. The Shionogi Phase II study findings contribute important new information about the safety and efficacy of peramivir in patients with acute uncomplicated influenza."

"We are encouraged by the positive results of this Phase II study testing a single dose of i.v. peramivir in the outpatient setting," stated Jon P. Stonehouse, President and Chief Executive Officer of BioCryst. "As recently announced, we have initiated a Phase II study of intramuscular peramivir in a similar setting as the Shionogi study, which will add further confirmation of this promising compound's role in addressing seasonal influenza."

In February 2007, BioCryst and Shionogi entered into an exclusive license agreement under which Shionogi obtained rights to develop and commercialize peramivir in Japan for the treatment of seasonal and potentially life-threatening human influenza. In exchange, BioCryst received a $14 million up-front payment and may also receive future clinical event milestone payments (up to $21 million) and commercial event milestone payments (up to $95 million) in addition to double-digit (between 10 percent and 20 percent range) royalty payments on product sales of peramivir. BioCryst retains all rights to commercialize peramivir in North America, Europe, and other countries outside of Japan and Korea.

Earlier this month, BioCryst commenced a Phase II study of intra-muscular (i.m.) peramivir in the outpatient setting comparing a single 600 mg dose to placebo in the treatment of seasonal influenza. The dose was selected based upon an analysis of a Phase I study of a new, more concentrated 150 mg/ml formulation of i.m. peramivir, as well as prior studies of peramivir in patients with influenza. The Phase II study will utilize the new, more concentrated 150 mg/ml formulation and needle length guidelines established in recently conducted pharmacokinetic studies.

About BioCryst

BioCryst Pharmaceuticals, Inc. is a leader in the use of crystallography and structure-based drug design for the development of novel therapeutics to treat cancer, cardiovascular diseases, autoimmune diseases, and viral infections. The Company is advancing multiple internal programs toward potential commercialization including forodesine HCl in oncology, BCX-4208 in psoriasis and peramivir in seasonal and life-threatening influenza. BioCryst is collaborating with Mundipharma for the development and commercialization of forodesine HCl in markets across Europe, Asia, Australia and certain neighboring countries. In January 2007, the U.S. Department of Health and Human Services (HHS) awarded a $102.6 million, four-year contract to BioCryst to advance development of peramivir to treat seasonal and life-threatening influenza. In February 2007, BioCryst established a partnership with Shionogi & Co. to develop and commercialize peramivir in Asia. For more information about BioCryst, please visit the Company's web site at http://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 the Phase II trial of BCX-4208 for psoriasis may not be successfully completed, 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.

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