BioCryst Reports Positive Results From a Phase 2 Study of Intravenous Peramivir for Outpatient Influenza

BIRMINGHAM, Ala., Oct 28, 2008 /PRNewswire-FirstCall via COMTEX News Network/ -- A Single Dose of Peramivir is Effective and Well-Tolerated at Both 300 mg and 600 mg Dose Levels

BioCryst Pharmaceuticals, Inc. (Nasdaq: BCRX) today announced that a double-blind, placebo-controlled, Phase 2 study of intravenous (i.v.) peramivir, administered via a single dose injection in outpatients with acute, uncomplicated influenza, met its primary endpoint of time to alleviation of symptoms for both the 300 mg dose (p=0.0046) and 600 mg dose (p=0.0046). The study was sponsored by BioCryst's partner for peramivir, Shionogi & Co., Ltd.

The poster titled, "A Double-Blind, Placebo-Controlled Study of Intravenous Peramivir in Acute Influenza Patients" (Poster Session # 302: Respiratory Viruses I: Influenza and RSV) will be presented on Tuesday, October 28 from 12:15 p.m. - 1:15 p.m. Eastern Time in Hall C by Dr. Shigeru Kohno, Dean, Nagasaki University Graduate School of Medicine and Professor, Infection Immunology Department, Nagasaki University Graduate School of Medicine, Dentistry and Pharmaceutical Sciences.

"This Phase 2 study was a critical test of peramivir, which demonstrated for the first time that a single administration of this potent neuraminidase inhibitor can be effective in treating seasonal influenza," said Dr. William P. Sheridan, Chief Medical Officer of BioCryst. "The promising data in outpatient influenza highlights the potential of the compound as a novel and effective influenza therapy and we look forward to learning more about the clinical advantages of peramivir in the upcoming Shionogi-sponsored Phase 3 program."

The randomized, double-blind, placebo-controlled, Phase 2 study conducted in Japan enrolled 300 patients age 20 to 64, who tested positive by rapid antigen test (RAT) for influenza within 48 hours of symptom onset. Of the 300 patients randomized, 296 were included in the intent-to-treat infected population; 99 received 300 mg peramivir i.v., 97 received peramivir 600 mg i.v. and 100 received placebo i.v. The primary endpoint of the study was time to alleviation of symptoms. Other endpoints included change from baseline in composite symptom score, time-weighted change in influenza virus titers from baseline to two days following infusion, pharmacokinetics and safety.

Both doses of peramivir significantly reduced the time to alleviation of symptoms in influenza patients by 32 to 33 percent compared to placebo: hazard ratios were 0.681 for 300 mg dose and 0.666 for the 600 mg dose (adjusted p=0.0046 for both comparisons). The median time to alleviation of symptoms was 59.1 hours for those receiving the 300 mg dose, 59.9 hours for those receiving the 600 mg dose and 81.8 hours for those receiving placebo. In addition, change from baseline in the composite symptom score was significantly improved in both the peramivir 300 mg and 600 mg arms compared to the placebo arm, as early as 24 hours after the start of treatment (p=0.0032 and p=0.0109, respectively). There was a significant difference between peramivir 600 mg and placebo in time-weighted change in influenza virus titers from baseline to two days following infusion (p=0.0027). Peramivir was generally well-tolerated, with an adverse event profile similar to that of placebo. Pharmacokinetic profiles of i.v. peramivir in influenza patients were similar to those seen in healthy subjects.

About the Shionogi & Co., Ltd. Partnership

In February 2007, BioCryst and Shionogi & Co., Ltd. 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. Earlier this year, Shionogi's rights were extended to include Taiwan. In 2007, 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, Taiwan and Korea.

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, a 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 Shionogi & Co., Ltd.

Shionogi & Co., Ltd., one of Japan's largest research-based pharmaceutical companies develops, manufactures, distributes, imports and exports pharmaceuticals and diagnostics. Shionogi aims to provide innovative medicines which make a positive contribution to world-wide health. For additional company information, please visit Shionogi on the World Wide Web at http://www.shionogi.co.jp.

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 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 a previous Phase 2 clinical trial of intramuscular 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.

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