



BioCryst Pharmaceuticals Reports Positive Results of Shionogi & Co. Sponsored Phase 3 Studies of i.v. Peramivir for Influenza

BIRMINGHAM, Ala., July 17, 2009 /PRNewswire-FirstCall via COMTEX News Network/ -- BioCryst Pharmaceuticals (Nasdaq: BCRX) today announced positive results from two Phase 3 studies of intravenous (i.v.) peramivir in patients with seasonal influenza. The studies were sponsored by BioCryst's partner Shionogi & Co., Ltd. of Osaka, Japan and conducted during the 2008-2009 influenza season. Shionogi and Green Cross Corporation, the license holder of peramivir in Korea, co-conducted the portion of the studies in Korea.

In patients with uncomplicated seasonal influenza, Shionogi conducted a three-armed, multi-center, randomized, double-blind, multi-national Phase 3 study of i.v. peramivir that compared the efficacy and safety of a single dose of peramivir (either 300 mg or 600 mg) and treatment with oral oseltamivir phosphate 75 mg (Tamiflu((R))) twice a day for five days. A total of 1,099 patients were enrolled at 146 centers (Japan:100; Korea:25; Taiwan:21). Both the 300 mg and 600 mg single dose peramivir groups demonstrated non-inferiority for the primary endpoint, time to alleviation of symptoms (TTAS), compared to the oseltamivir group. The medians for TTAS for the peramivir 300 mg, peramivir 600 mg and oseltamivir groups were 78.0 hours, 81.0 hours and 81.8 hours, respectively.

Additionally, Shionogi conducted a double-blind, multi-center Phase 3 study of i.v. peramivir with dosing over multiple days. The study enrolled 42 influenza patients at high-risk of serious complications due to one or more qualifying conditions: diagnosis with poorly controlled diabetes mellitus, a chronic respiratory disease requiring pharmacotherapy, or current treatment with any immunosuppressive drug. Peramivir was administered at 300 mg or 600 mg per day, and the duration was adjusted (up to five days) on a case-by-case basis, depending on the patient's temperature and clinical condition. In this study, the median time to alleviation of symptoms in all 37 evaluable patients treated with either 300 mg or 600 mg peramivir daily was 68.6 hours.

i.v. peramivir 300 mg and 600 mg in both single and multiple doses were generally safe and well-tolerated in these trials. Further analyses of the study data, including secondary efficacy endpoints and detailed safety is underway. Additional data will be submitted for presentation at an upcoming medical meeting.

"The clinical outcomes of these Phase 3 studies are important, especially during the declared influenza pandemic, as they indicate the promise of peramivir as a treatment for influenza," commented Dr. William P. Sheridan, Chief Medical Officer of BioCryst. "The need for additional anti-viral treatment options for influenza remains high. BioCryst is currently finalizing its plans for peramivir Phase 3 studies intended to support U.S. regulatory approval, while continuing to support the pre-emergency use authorization review of peramivir by the U.S. Food & Drug Administration."

"This data represents a significant milestone for BioCryst -- the first Phase 3 studies successfully conducted with a drug candidate discovered by BioCryst," said Jon P. Stonehouse, President and Chief Executive Officer of BioCryst. "We congratulate Shionogi on the success of these rapidly completed studies, which have the potential to lead to the first regulatory approval for peramivir."

Shionogi has stated that the Company is making its best effort to file its New Drug Application and to receive a manufacturing approval as soon as possible in Japan.

About Peramivir

Peramivir is an anti-viral agent that inhibits the interactions of influenza neuraminidase, an enzyme which is critical to the spread of influenza within a host. Peramivir has demonstrated clinical activity and safety in prior human studies. In laboratory tests, peramivir has shown activity against various viral strains, including the novel influenza A (H1N1) virus. In the U.S., BioCryst is preparing plans for additional Phase 3 studies of i.v. peramivir to support product registration. Additionally, i.v. peramivir is currently undergoing a pre-emergency use authorization (EUA) review.

About the Shionogi & Co., Ltd. Partnership

In February 2007, BioCryst & 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 influenza. In 2008, Shionogi's rights were extended to include Taiwan. Under the terms of the agreement, BioCryst may receive future clinical and commercial event milestone payments up to \$116 million, as well as double digit royalty payments on product sales

of peramivir. BioCryst retains its rights to commercialize peramivir in countries outside of Japan, Taiwan and South Korea.

About BioCryst

BioCryst is a biopharmaceutical company that has developed a diverse 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 peramivir may not receive emergency use authorization; that the U.S. government may choose not to ship peramivir to the CDC Strategic National Stockpile; that to the extent peramivir is used as a treatment for H1N1 flu (or other strains of flu), there can be no assurance that it will prove effective; that HHS may further condition, reduce or eliminate future funding of the peramivir program; that ongoing peramivir clinical trials or our peramivir program in general 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 peramivir or our other product candidates may not receive required regulatory clearances from the FDA or other regulatory agencies; 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 and subsequently amended Jan 23, 2009), 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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