



BioCryst's Partner Shionogi Files for Peramivir Regulatory Approval in Japan

BIRMINGHAM, Ala., Nov 04, 2009 /PRNewswire-FirstCall via COMTEX News Network/ -- BioCryst Pharmaceuticals, Inc. (Nasdaq: BCRX) today announced that its partner, Shionogi & Co., Ltd. has filed a New Drug Application (NDA) in Japan to seek regulatory approval for intravenous (i.v.) peramivir to treat patients with influenza. As a consequence of this filing, BioCryst will receive a regulatory milestone payment of \$7 million under its agreement with Shionogi.

"We congratulate Shionogi on this accomplishment and the great effort its team made to swiftly prepare the filing. This is the first application for marketing approval of peramivir in any country and it is a significant landmark for BioCryst," said Jon P. Stonehouse, President and Chief Executive Officer of BioCryst. "BioCryst continues to work with U.S. agencies, other governments and our partners to provide i.v. peramivir as a treatment option for hospitalized patients with influenza during the ongoing pandemic, and to complete the development of peramivir through the traditional regulatory pathway."

About peramivir

Peramivir is a potent, intravenously administered anti-viral agent that rapidly delivers high plasma concentrations to the sites of infection. Discovered by BioCryst, peramivir 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 pandemic H1N1 swine flu origin viral strains. Peramivir has been studied in patients with complicated and uncomplicated influenza. On October 23, 2009, BioCryst announced that the U.S. Food and Drug Administration (FDA) issued an emergency use authorization (EUA) for i.v. peramivir in certain adult and pediatric patients with confirmed or suspected 2009 H1N1 influenza infection who are admitted to a hospital. Additional information regarding the peramivir EUA is available on the web at: <http://www.cdc.gov/h1n1flu/eua/>.

About Influenza

According to the CDC, on average in the U.S., approximately 200,000 people are hospitalized from flu complications and 36,000 people die from flu-related causes each year. Influenza (the flu) is a contagious respiratory illness caused by [influenza viruses](#).

More information is available at:

<http://www.cdc.gov/flu/>

<http://www.hhs.gov/pandemicflu/plan/pdf/HHSPandemicInfluenzaPlan.pdf>

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 influenza. In 2008, Shionogi's rights were extended to include Taiwan. Under the terms of the agreement, BioCryst may receive future regulatory and commercial event milestone payments up to \$102 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 Pharmaceuticals designs, optimizes and develops novel small-molecule pharmaceuticals that block key enzymes involved in infectious diseases, cancer and inflammatory diseases. BioCryst has progressed two novel compounds into late-stage pivotal clinical trials; peramivir, an anti-viral for influenza, and forodesine, a purine nucleoside phosphorylase (PNP) inhibitor for cutaneous T-cell lymphoma (CTCL). Utilizing crystallography and structure-based drug design, BioCryst continues to discover additional compounds and to progress others through pre-clinical and early development to address the unmet medical needs of patients and physicians. 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 Limited 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 the U.S. government and ex-U.S. governments may choose not to issue a request for peramivir to treat influenza or such requests, if any, may not result in an order or such order, if any, may not be profitable for BioCryst; 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 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 pre-clinical 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 and partnerships 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 cash 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, 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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