# BioCryst's Partner Shionogi Receives Marketing & Manufacturing Approval For Peramivir in Japan

BIRMINGHAM, Ala., Jan 13, 2010 /PRNewswire via COMTEX News Network/ -- BioCryst Pharmaceuticals, Inc. (Nasdaq: BCRX) today announced that its partner, Shionogi & Co., Ltd. has received marketing and manufacturing approval for intravenous (i.v.) peramivir to treat patients with influenza in Japan. Shionogi intends to commercially launch peramivir under the commercial name RAPIACTA in Japan, pending the product's National Health Insurance (NHI) price listing.

As a result of this approval, BioCryst will receive a third and final regulatory milestone payment of $7 million under its license agreement with Shionogi. BioCryst may receive future commercial event milestone payments of up to $95 million from Shionogi.

"This first approval of a BioCryst discovered drug is a major step in our journey towards building an enduring and successful biopharmaceutical company," said Jon P. Stonehouse, President and Chief Executive Officer of BioCryst. "We congratulate Shionogi on receiving rapid approval of peramivir, one of the quickest marketing authorizations ever granted by the Japanese authorities. BioCryst continues to work with other governments and our partners to make i.v. peramivir available as a treatment option for hospitalized patients with influenza during the ongoing pandemic, and to complete the development of peramivir as a seasonal influenza treatment in the future."

Shionogi received the indications of single dose administration of 300 mg i.v. peramivir for adult uncomplicated seasonal influenza infection, as well as single and multiple dose administration of 600 mg i.v. peramivir for the patients at high-risk for complications associated with influenza. Shionogi is authorized to supply peramivir as either a 300 mg i.v. bag or a 150 mg vial for i.v. drip infusion.

Additionally, Shionogi announced that it has completed clinical studies for pediatric patients and the Company will make its best efforts to file an additional application for pediatric use of RAPIACTA within its current fiscal year, which ends March 31, 2010.

**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 multiple influenza strains, including pandemic H1N1 swine origin flu viral strains. Peramivir has been studied in over 1800 patients with complicated and uncomplicated influenza. Green Cross Corp. has filed for regulatory approval in Korea. On October 23, 2009, BioCryst announced that the U.S. Food and Drug Administration (FDA) issued an emergency use authorization (EUA) for intravenous peramivir in certain adult and pediatric patients with confirmed or suspected 2009 H1N1 influenza A 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 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 forcutaneous 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. 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 additional orders for peramivir and such orders, 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 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.

BCRXW

SOURCE BioCryst Pharmaceuticals, Inc.