February 25, 2014

BioCryst Announces Peramivir NDA Acceptance by the FDA

RESEARCH TRIANGLE PARK, N.C., Feb. 25, 2014 (GLOBE NEWSWIRE) -- BioCryst Pharmaceuticals, Inc. (Nasdaq:BCRX), a pharmaceutical company focused on the development and commercialization of treatments for rare and infectious diseases, today announced that the U.S. Food and Drug Administration (FDA) has accepted for review the New Drug Application (NDA) for intravenous (i.v.) peramivir that was submitted to the FDA in December 2013. The FDA assigned the NDA a standard review time, resulting in a PDUFA (Prescription Drug User Fee Act) action date of December 23, 2014. The FDA has informed BioCryst that at this time, it does not plan to hold an Advisory Committee review of the NDA.

"We are pleased that BioCryst's first NDA filing has been accepted by the FDA. We believe the approval of peramivir and its mode of i.v. administration would benefit many influenza patients, including those who cannot tolerate treatment by oral or inhaled administration," said Jon P. Stonehouse, President & Chief Executive Officer. "BioCryst is preparing to make peramivir available in the U.S. during the 2014-15 influenza season, provided approval is granted within that timeframe."

In June 2013, BioCryst completed a pre-NDA meeting with the FDA regarding peramivir. BioCryst reached agreement with FDA regarding all requirements for a complete NDA submission. The peramivir NDA submission included results in over 2,700 subjects treated with peramivir in 27 clinical trials. Peramivir has been approved in Japan and Korea. It is estimated that more than one million patients have received peramivir treatment to date.

About Peramivir

Peramivir is a potent, intravenously administered investigational 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 H7N9 and pandemic H1N1 swine flu viral strains. Peramivir has been developed under a $234.8 million contract from BARDA/HHS. In January 2010, Shionogi & Co., Ltd. launched intravenous peramivir in Japan under the name RAPIACTA® to treat patients with influenza and in August 2010, Green Cross Corporation announced that it had received marketing and manufacturing authorization for i.v. peramivir in Korea to treat patients with influenza A & B viruses, including H1N1 and avian influenza. For more information about peramivir, please visit BioCryst's Web site at http://www.biocryst.com/peramivir.

About BioCryst Pharmaceuticals

BioCryst Pharmaceuticals designs, optimizes and develops novel small molecule drugs that block key enzymes involved in infectious and rare diseases, with the goal of addressing unmet medical needs of patients and physicians. BioCryst's core development programs include BCX4161 and two next generation oral inhibitors of plasma kallikrein for hereditary angioedema; peramivir, a viral neuraminidase inhibitor for the treatment of influenza; and BCX4430, a broad spectrum antiviral for hemorrhagic fevers. For more information, please visit the Company's website 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 BioCryst's 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 FDA may not provide regulatory approval for any use of peramivir or that the approval may be limited; that BARDA/HHS may further condition, reduce or eliminate future funding of the peramivir program; that the Company may not be able to access adequate capital to move peramivir forward; the Company may not be able to successfully commercialize peramivir on its own; that the Company may not reach favorable agreements with potential pharmaceutical and biotechnology partners for the commercialization of peramivir; that peramivir may never be purchased by any government entity for stockpiling. 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, 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 BioCryst's projections and forward-looking statements.

BCRXW

CONTACT: Robert Bennett,

BioCryst Pharmaceuticals,

+1-919-859-7910

Source: BioCryst Pharmaceuticals