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BioCryst Announces RAPIVAB(TM) Trial Results for the Treatment of Influenza at the ICAAC 2014 Meeting

RESEARCH TRIANGLE PARK, N.C., Sept. 6, 2014 (GLOBE NEWSWIRE) -- BioCryst Pharmaceuticals, Inc. (Nasdaq:BCRX) today announced trial results related to RAPIVAB™ (peramivir injection), a neuraminidase inhibitor (NAI) for the treatment of influenza at the Interscience Conference on Antimicrobial Agents & Chemotherapy (ICAAC) in Washington, D.C., September 5-9, 2014.

"Based on clinical trial data, peramivir is the first neuraminidase inhibitor (NAI) that has shown to be safe and effective as a single-dose therapy for patients with acute, uncomplicated influenza," said presenting author Richard Whitley, M.D, University of Alabama at Birmingham. "In a combined analysis of two randomized placebo-controlled trials, a single dose of peramivir administered parenterally alleviated flu symptoms, including fever, significantly faster than placebo and reduced viral shedding."

The Oral Presentation Number V-1297 titled "Single Dose Peramivir for the Treatment of Acute Seasonal Influenza: Integrated Analysis of Efficacy and Safety from Two Placebo-controlled Trials," verifies that a single dose intramuscular (I.M.) peramivir was generally safe and well tolerated, and reduced the duration of clinical symptoms and viral shedding in patient with acute uncomplicated influenza. The median time to alleviation of influenza symptoms after treatment with peramivir 300 mg was 113.2 hours, compared to 134.8 hours for placebo (p=0.161 adjusted for smoking behavior, influenza season and virus type, p=0.047 unadjusted). Median time to resolution of fever was reduced by 24.0 hours after treatment with peramivir 300 mg compared with placebo (p=0.004). Influenza viral shedding was significantly decreased during the first 48 hours after peramivir treatment (p=0.009) and detection of post-treatment viruses with decreased susceptibility to NAIs was rare. The treatment effect size is similar to that reported for other NAIs.

Poster Presentation Number A-012 titled "Single Dose Injections of I.V. and I.M. peramivir are Bioequivalent and Well Tolerated," presents data from two clinical pharmacology bioequivalence studies in healthy subjects. These studies confirmed that exposure to peramivir dosed by either IV infusion or IM injection is equivalent.

The presentation and poster are available at the Company's peramivir publications page.

The peramivir New Drug Application (NDA) for the indication of treatment of acute uncomplicated influenza in adults is currently under regulatory review by FDA, with a PDUFA data of Dec 23, 2014. If approved, peramivir would be marketed as RAPIVAB™ (peramivir injection).

About RAPIVAB

RAPIVAB is a potent, intravenously administered investigational anti-viral agent that rapidly delivers high plasma concentrations to the sites of infection. Discovered by BioCryst, RAPIVAB inhibits the interactions of influenza neuraminidase, an enzyme which is critical to the spread of influenza within a host. In laboratory tests, RAPIVAB has shown activity against multiple influenza strains, including H7N9 and pandemic H1N1 swine flu viral strains. RAPIVAB was developed under a $234.8 million contract from BARDA/HHS. In January 2010, Shionogi & Co., Ltd. launched 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 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

BioCryst Pharmaceuticals designs, optimizes and develops novel small molecule drugs that block key enzymes involved in rare diseases. BioCryst currently has several ongoing development programs: oral inhibitors of plasma kallikrein for hereditary angioedema, including BCX4161 and several second generation compounds; peramivir, a viral neuraminidase inhibitor for the treatment of influenza, and BCX4430, a broad spectrum viral RNA polymerase inhibitor. 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 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 FDA may not provide regulatory approval for any use of peramivir or that the approval may be limited; that regulatory or other issues with our manufacturer may impact peramivir approval or may impact the supply of peramivir in the event of regulatory approval; the Company may not be able to successfully commercialize 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.

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