



November 7, 2012

BioCryst Announces Outcome from the Peramivir Phase 3 Interim Analysis

BioCryst management to discuss outcome during its third quarter 2012 results call now scheduled November 8 at 8:30 a.m. ET

RESEARCH TRIANGLE PARK, N.C.--(BUSINESS WIRE)-- [BioCryst Pharmaceuticals, Inc.](#) (NASDAQ:BCRX) today announced completion of the planned interim analysis of the peramivir [Phase 3](#) trial in patients admitted to the hospital with serious influenza. The difference between peramivir and control groups for the primary endpoint was small and the recalculated sample size was greater than the predefined futility boundary of 320 subjects. Based on this information, the independent data monitoring committee (DMC) recommended that the study be terminated for futility. No unexpected adverse events were identified and the DMC expressed no concerns about the safety of peramivir.

"The goal of this analysis was to reassess the sample size required for the trial, and to make adjustments to the study if necessary. Based on the DMC recommendation, we have suspended enrollment of patients in the trial," said [Dr. William P. Sheridan, Senior Vice President & Chief Medical Officer](#) of BioCryst Pharmaceuticals. "We are proceeding with a full analysis of unblinded data from the trial, and a final decision will be made following completion of the analysis and further discussions with our development partners; however, it is unlikely that peramivir development for US registration will continue."

BioCryst has shared the DMC recommendation with the U.S. Department of Health and Human Services Biomedical Advanced Research and Development Authority (HHS/BARDA) and other development partners.

The interim analysis will be discussed by BioCryst management during the Company's third quarter 2012 results conference call and webcast on Thursday, November 8, 2012 at 8:30 a.m. Eastern Time.

Phase 3 Development of Peramivir

The peramivir Phase 3 U.S. registration trial ("301") is a multicenter, randomized, double-blind, controlled study to evaluate the efficacy and safety of 600 mg i.v. peramivir administered once-daily for five days in addition to standard of care (SOC), compared to SOC alone, in adults and adolescents who are hospitalized due to serious influenza. In February 2011, the primary efficacy analysis of the trial was amended to focus on a subset of approximately 160 patients not treated with neuraminidase inhibitors as SOC, in order to provide the greatest opportunity to demonstrate a statistically significant peramivir treatment effect.

A total of 405 patients were enrolled in the overall trial population at the time of the interim analysis data cutoff. The interim analysis was conducted on 119 patients enrolled in the primary efficacy population. The interim analysis evaluated the difference in time to clinical resolution between the peramivir group and the control group for the subjects enrolled to date, and estimated the sample size for the primary efficacy analysis population required to maintain adequate power and to show statistical significance in the final study analysis.

Further details regarding the Phase 3 trial are available at: <http://clinicaltrials.gov/ct2/show/NCT00958776>.

About Influenza

The influenza virus causes an acute viral disease of the respiratory tract. Unlike the common cold and some other respiratory infections, seasonal flu can cause severe illness, resulting in life-threatening complications. According to the CDC, an estimated 5% to 20% of the American population suffers from influenza annually, and there are approximately 3,000 to 49,000 flu-related deaths per year in the U.S. Most at risk are young children, the elderly and people with seriously compromised immune systems.

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 pandemic H1N1 swine origin flu viral strains. Peramivir is being developed under a \$234.8

million contract from HHS/BARDA. In January 2010, Shionogi & Co., Ltd. launched intravenous (i.v.) 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

BioCryst Pharmaceuticals designs, optimizes and develops novel small molecule drugs that block key enzymes involved in infectious and inflammatory diseases. BioCryst currently has two late-stage development programs: peramivir, a viral neuraminidase inhibitor for the treatment of influenza, and ulodesine (BCX4208), a purine nucleoside phosphorylase (PNP) inhibitor for the treatment of gout. In addition, BioCryst is developing two preclinical compounds: BCX5191, a nucleoside analog inhibitor of HCV RNA polymerase (NS5B) for hepatitis C, and BCX4161, an oral inhibitor of plasma kallikrein for hereditary angioedema. Utilizing state-of-the-art structure-guided drug design and crystallography, BioCryst continues to discover innovative compounds with the goal of addressing unmet medical needs of patients and physicians. 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 HHS/BARDA may further condition, reduce or eliminate future funding of the peramivir program; that BioCryst or its licensees may not be able to enroll the required number of subjects in planned clinical trials of its product candidates and that such clinical trials may not be successfully completed; that the company or its licensees may not commence as expected additional human clinical trials with product candidates; that the FDA may require additional studies beyond the studies planned for product candidates or may not provide regulatory clearances which may result in delay of planned clinical trials, clinical hold with respect to such product candidate or the lack of market approval for such product candidate; that ongoing and future preclinical and clinical development may not have positive results; that the company or its licensees may not be able to continue future development of current and future development programs; that such development programs may never result in future product, license or royalty payments being received; that the companies may not be able to retain its current pharmaceutical and biotechnology partners for further development of its product candidates or may not reach favorable agreements with potential pharmaceutical and biotechnology partners for further development of product candidates; that its actual cash burn rate may not be consistent with its expectations; that 2012 operating expenses and cash usage will be within management's expected ranges. 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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