



April 1, 2013

BioCryst Pharmaceuticals Provides Update Regarding Peramivir

RESEARCH TRIANGLE PARK, N.C.--(BUSINESS WIRE)-- [BioCryst Pharmaceuticals, Inc.](#) (NASDAQ:BCRX) today announced that it received a preliminary comment letter from the U.S. Food & Drug Administration (FDA) that outlines a pathway by which BioCryst could file a New Drug Application (NDA) seeking regulatory approval of intravenous (i.v.) [peramivir](#). The letter was sent in response to questions BioCryst submitted to the FDA in advance of an upcoming Type C regulatory meeting regarding i.v. peramivir. The FDA also suggested the Company request a pre-NDA meeting to reach agreement on a complete NDA submission and to address review issues identified in its preliminary comment letter.

BioCryst also received written notification from the Department of Health and Human Services in the form of a Stop-Work Order directing the Company to cease work on peramivir under its U.S. Government contract, except for certain activities primarily related to the upcoming FDA Type C meeting which is scheduled. The notification confirmed that the Biomedical Advanced Research and Development Authority (BARDA/HHS) will continue to support and fund certain activities that are necessary to achieve immediate milestones, as well as activities deemed essential to maintain compliance with FDA regulations or to fulfill pending FDA requests. Following an In-Process Review (IPR) meeting, which BioCryst anticipates in the second quarter, BARDA/HHS is expected to determine the path forward for the contract.

"We are encouraged by these recent communications, and we look forward to advancing our peramivir discussions with the FDA and BARDA/HHS. Our ultimate objective is the approval of peramivir as an intravenous treatment option that could benefit patients in the United States," said [Jon P. Stonehouse, President & Chief Executive Officer](#). "The Stop—Work Order is understandable, as it focuses the scope of reimbursable activities to those that are essential and supportive to continuing regulatory communications, with the objective of preparing an NDA submission. If the conversations with the FDA and BARDA/HHS are successful, BioCryst stands ready to file an NDA for peramivir as soon as feasible."

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 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 Pharmaceuticals

BioCryst Pharmaceuticals designs, optimizes and develops novel small molecule drugs that block key enzymes involved in infectious and inflammatory diseases, with the goal of addressing unmet medical needs of patients and physicians. BioCryst currently has two late-stage development programs: peramivir, a viral neuraminidase inhibitor for the treatment of influenza, and [ulodesine](#), a purine nucleoside phosphorylase (PNP) inhibitor for the treatment of gout. In addition, BioCryst has several early-stage programs: [BCX4161](#) and a next generation oral inhibitor of plasma kallikrein for hereditary angioedema 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 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, especially associated with the peramivir program, which may result in delay of planned clinical trials, may impose a clinical hold with respect to such product candidate, or may withhold market approval for product candidates; that BARDA/HHS may further condition, reduce or eliminate future funding of the peramivir program; that BioCryst may never file an NDA for peramivir approval and peramivir may never be approved for any use by the FDA; 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; and that the Company 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. 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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Source: BioCryst Pharmaceuticals, Inc.

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