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## BioCryst Files Peramivir NDA for the Treatment of Influenza

RESEARCH TRIANGLE PARK, N.C.--(BUSINESS WIRE)-- [BioCryst Pharmaceuticals, Inc.](#) (NASDAQ:BCRX), a pharmaceutical company focused on the development and commercialization of treatments for rare and infectious diseases, today announced that it has submitted a New Drug Application (NDA) filing for intravenous (i.v.) [peramivir](#) to the U.S. Food & Drug Administration (FDA). BioCryst is seeking an indication as the first i.v. neuraminidase inhibitor approved in the U.S. for the treatment of acute uncomplicated influenza in adults. Peramivir is approved in Japan and Korea for the treatment of influenza.

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 includes results in over 2700 subjects treated with peramivir in 27 clinical trials.

"BioCryst's first NDA filing represents an important milestone in the history of the company. We are excited about the potential approval of peramivir as an i.v. treatment option that could benefit influenza patients in the United States," said [Jon P. Stonehouse, President & Chief Executive Officer](#). "BioCryst is preparing to make peramivir available in the U.S. in time for the 2014-15 influenza season, in the event approval is received in that timeframe. We thank BARDA/HHS for enabling the successful completion of this program."

BioCryst requested and was granted a small business waiver of the application fee for the peramivir NDA filing. The waiver confirmation was submitted with the NDA filing.

### 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](http://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; that the Company may not reach favorable agreements with potential pharmaceutical and biotechnology partners for the commercialization of peramivir. 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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