



January 30, 2017

BioCryst Announces the Acceptance of Peramivir MAA Filing by the European Medicines Agency

RESEARCH TRIANGLE PARK, N.C., Jan. 30, 2017 (GLOBE NEWSWIRE) -- [BioCryst Pharmaceuticals, Inc.](#) (NASDAQ:BCRX), a pharmaceutical company focused on the development and commercialization of treatments for rare diseases, announced today that the [European Medicines Agency](#) (EMA) has accepted the filing of its peramivir Marketing Authorization Application (MAA) for treatment of symptoms typical of influenza in adults 18 years and older. The acceptance of the MAA begins the review process by the EMA under the centralized licensing procedure for all 28 member states of the European Union, Norway and Iceland. Peramivir's efficacy has been demonstrated when treatment is initiated within two days of first onset of symptoms.

"This filing brings BioCryst and Seqirus one step closer to making the only single-dose, I.V. influenza therapy available to an important market, the European Union," said [Jon P. Stonehouse, President & Chief Executive Officer](#).

Seqirus, a leader in influenza prevention through the supply of seasonal and pandemic influenza vaccines to global markets, will commercialize ALPIVAB™.

About Peramivir

Peramivir is an intravenous (I.V.) viral neuraminidase inhibitor approved in multiple countries, including the United States, for the treatment of influenza in patients who have been symptomatic for no more than two days. Efficacy of peramivir is based on clinical trials of naturally occurring influenza in which the predominant influenza infections were influenza A virus; a limited number of subjects infected with influenza B virus were enrolled. The efficacy of peramivir could not be established in patients with serious influenza requiring hospitalization. In clinical studies, side effects with peramivir were similar to placebo. The most common adverse reaction was diarrhea (peramivir 8% vs 7% placebo). Similar to other neuraminidase inhibitors, there is a risk of neuropsychiatric events (confusion, delirium) and serious skin reactions. Visit www.rapivab.com to learn more. ALPIVAB is a trademark of Seqirus UK Limited.

About BioCryst Pharmaceuticals

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: BCX7353 and second generation oral inhibitors of plasma kallikrein for hereditary angioedema, and galidesivir, a broad spectrum viral RNA polymerase inhibitor that is a potential treatment for filoviruses. Peramivir, a viral neuraminidase inhibitor, is approved for the treatment of influenza, in the U.S., Canada, Japan, Taiwan and Korea. Post-marketing commitment development activities are ongoing, as well as other activities to support additional peramivir regulatory approvals. 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 EMA may not provide regulatory approval for any use of peramivir or that the approval may be limited. 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.

CONTACT:

Robert Bennett,

BioCryst Pharmaceuticals,

+1-919-859-7910

 [Primary Logo](#)

Source: BioCryst Pharmaceuticals

News Provided by Acquire Media