BioCryst's BCX7353 Receives European Regulatory Designations for the Treatment of Hereditary Angioedema

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EMA Grants Orphan Designation
UK MHRA Grants Promising Innovative Medicine Designation

RESEARCH TRIANGLE PARK, N.C., May 24, 2018 (GLOBE NEWSWIRE) -- BioCryst Pharmaceuticals, Inc. (NASDAQ:BCRX), a pharmaceutical company focused on the development and commercialization of treatments for rare diseases, today announced that the European Medicines Agency's ("EMA") Committee for Orphan Medicinal Products ("COMP") issued a positive opinion on BioCryst's application for orphan designation of BCX7353 for the treatment of hereditary angioedema ("HAE"). In addition, the United Kingdom's Medicines and Healthcare products Regulatory Agency ("MHRA") has granted a Promising Innovative Medicine ("PIM") designation to BCX7353.

The positive opinion issued by COMP is expected to be adopted by the European Commission within 30 days. Orphan Drug Designation in Europe is available to companies developing products intended to treat a life-threatening or chronically debilitating condition that affects fewer than five in 10,000 persons in the European Union ("EU"). This designation allows for financial and regulatory incentives that include a 10-year period of marketing exclusivity in the EU after product approval. BCX7353 has previously received Orphan Drug Designation in the United States from the Food and Drug Administration.

A PIM designation is an early indication that a medicinal product is a promising candidate for the Early Access to Medicines Scheme ("EAMS") in the United Kingdom, which supports products intended for the treatment, diagnosis or prevention of a life-threatening or seriously debilitating condition, with the potential to address an unmet medical need.

"We are pleased to receive these important regulatory designations granted to BCX7353. These provide further support for the potential for BCX7353 to address a clear unmet medical need with an oral treatment for patients with HAE," said Jon P. Stonehouse, President & Chief Executive Officer.

About BCX7353

Discovered by BioCryst, BCX7353 is a novel, oral, once-daily, selective inhibitor of plasma kallikrein currently in development for the prevention and treatment of angioedema attacks in patients diagnosed with HAE. BCX7353 has been generally safe and well tolerated in the Phase 2 APeX-1 clinical trial. BioCryst is currently conducting the Phase 3 APeX-2 clinical trial and the long-term safety APeX-S clinical trial, both evaluating two dosage strengths of BCX7353 administered orally once-daily as a preventive treatment to reduce the frequency of attacks in patients with HAE. BioCryst is also conducting the ZENITH-1 clinical trial. ZENITH-1 is a proof-of-concept Phase 2 clinical trial testing an oral liquid formulation of BCX7353 for the treatment of acute angioedema attacks.

About BioCryst Pharmaceuticals

BioCryst Pharmaceuticals designs, optimizes and develops novel small-molecule medicines that address both common and rare conditions. BioCryst has several ongoing development programs including BCX7353, an oral treatment for hereditary angioedema, galidesivir, a potential treatment for filoviruses, and a preclinical program to develop oral Alk-2 inhibitors for the treatment of fibrodysplasia ossificans progressive ("FOP"). RAPIVAB ® (peramivir injection), a viral neuraminidase inhibitor for the treatment of influenza, is BioCryst's first approved product and has received regulatory approval in the U.S., Canada, Australia, Japan, Taiwan, Korea and the European Union. Post-marketing commitments for RAPIVAB are ongoing. 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 are 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 developing any HAE product candidate may take longer or may be more expensive than planned; that ongoing and future preclinical and clinical development of HAE drug candidates (including ZENITH-1, APeX-2 and APeX-S) may not have positive results; that BioCryst may not be able to enroll the required number of subjects in planned clinical trials of product candidates; that the Company may not advance human clinical trials with product candidates as expected; that the FDA, EMA or other applicable regulatory agency 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, or may impose a clinical hold with respect to such product candidate, or withhold market approval for 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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