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BioCryst Announces Initiation of a Phase 1 Clinical Trial of BCX7353 for the Treatment of Hereditary Angioedema

RESEARCH TRIANGLE PARK, N.C., May 13, 2015 (GLOBE NEWSWIRE) -- [BioCryst Pharmaceuticals, Inc.](#) (Nasdaq:BCRX) today announced the initiation of a Phase 1 clinical trial to evaluate the safety, pharmacokinetics and pharmacodynamics of orally-administered BCX7353 in healthy volunteers. Discovered by BioCryst, BCX7353 is a novel, selective inhibitor of plasma kallikrein in development for prevention of attacks in patients with hereditary angioedema (HAE). BioCryst has successfully completed nonclinical safety studies, as well as *in vitro* studies in which BCX7353 exhibited potent and selective inhibition of plasma kallikrein. The pharmacokinetic profile of BCX7353 in preclinical studies indicates its potential for once daily dosing.

"We are pleased to advance BCX7353 into the clinic and look forward to reporting results from this trial during the third quarter 2015. The successful development of a once daily, orally administered prophylactic drug that is safe and efficacious would be a game changer and a convenient treatment alternative for patients suffering from HAE," said [Jon P. Stonehouse, President & Chief Executive Officer](#) of BioCryst.

The main goals of the Phase 1 clinical trial are to assess safety, characterize plasma drug levels in healthy volunteers, and estimate the extent of kallikrein inhibition achieved after oral dosing of BCX7353.

About Hereditary Angioedema

HAE is a rare, severely debilitating and potentially fatal genetic condition that occurs in approximately 1 in 50,000 people. HAE symptoms include recurrent episodes of edema in various locations, including the hands, feet, face, genitalia and airways. In addition, patients often have bouts of excruciating abdominal pain, nausea and vomiting that are caused by swelling in the intestinal walls. Airway swelling is particularly dangerous and can lead to death by asphyxiation. Further information regarding HAE can be found at www.haea.org.

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: oral inhibitors of plasma kallikrein for hereditary angioedema, including [BCX4161](#), BCX7353 and other second generation compounds, and [BCX4430](#), a broad spectrum viral RNA polymerase inhibitor. In December 2014, [RAPIVAB](#)TM (peramivir injection), a viral neuraminidase inhibitor for the treatment of influenza, was approved by the FDA and is available to treat flu patients in the U.S. 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 may not be able to enroll the required number of subjects in the clinical trial for BCX7353, that the BCX7353 trial may not have a favorable outcome or may not be successfully completed; that the Company may not commence additional human clinical trials for BCX7353; that the FDA or similar regulatory agency may refuse to approve subsequent studies, may impose a clinical hold for BCX7353 or other product candidates, or delay approval of clinical studies which may result in a delay of planned clinical studies and increase development costs of a product candidate; that the FDA may withhold market approval for product candidates; that ongoing and future preclinical and clinical development may not have positive results; that such development programs may never result in future product, license or royalty payments being received. 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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