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BioCryst Presents BCX4161 Phase 1 Trial and Kallikrein Inhibition Assay Results

RESEARCH TRIANGLE PARK, N.C., March 1, 2014 (GLOBE NEWSWIRE) -- [BioCryst Pharmaceuticals, Inc.](#) (Nasdaq:BCRX) announced the presentation of two scientific posters today at the [American Academy of Allergy, Asthma & Immunology \(AAAAI\) Annual Meeting](#) in San Diego describing phase 1 clinical trial results for BioCryst's potent and selective oral kallikrein inhibitor, [BCX4161](#), together with details of the Company's plasma kallikrein inhibition assay. BCX4161 is currently being evaluated in a Phase 2 clinical trial, [OPuS-1](#), as a potential treatment for the prevention of hereditary angioedema (HAE) attacks.

Poster #138 titled, "BCX4161, An Oral Kallikrein Inhibitor: Safety and Pharmacokinetic Results of a Phase 1 Study in Healthy Volunteers" summarizes BCX4161 safety and drug exposure in this first-in-human placebo-controlled clinical trial. Poster #143 titled, "A Simple, Sensitive and Selective Fluorogenic Assay to Monitor Plasma Kallikrein Inhibitory Activity of BCX4161 in Activated Plasma" describes an assay developed by BioCryst to determine the kallikrein inhibitory activity of BCX4161 in activated plasma from normal subjects and HAE patients. This assay is being used by BioCryst as a pharmacodynamic (PD) biomarker of drug effect in BCX4161 clinical trials.

BCX4161 was generally safe and well tolerated in the Phase 1 clinical trial, and there were no serious or dose limiting adverse events reported. Plasma levels of BCX4161 showed dose-related exposure consistent with saturable absorption, and plasma kallikrein inhibition correlated with BCX4161 levels. Plasma concentrations of BCX4161 met or exceeded the target range (25-40 ng/mL) predicted for efficacy in preventing HAE attacks for 80-90 percent of the dosing interval. The safety, pharmacokinetic (PK) and PD results of this phase 1 clinical trial supported the selection of the 400 mg TID regimen being tested in the ongoing OPuS-1 clinical trial.

"The research presented today at AAAAI expands our understanding of kallikrein inhibition and the activity of BCX4161. The PD assay results have provided a solid foundation for testing '4161's treatment effect in HAE patients," said [Dr. William P. Sheridan, Chief Medical Officer](#) at BioCryst. "We look forward to sharing results from OPuS-1 by the end of the second quarter."

About BCX4161

Discovered by BioCryst, BCX4161 is a novel, potent and selective inhibitor of plasma kallikrein in Phase 2 development for the prevention of attacks in patients with hereditary angioedema. By inhibiting plasma kallikrein, BCX4161 suppresses bradykinin production. Bradykinin is the mediator of acute swelling attacks in HAE patients.

About Hereditary Angioedema

HAE is a rare, severely debilitating and potentially fatal genetic condition that occurs in about 1 in 10,000 to 1 in 50,000 people. HAE symptoms include recurrent episodes of edema in various locations, including the hands, feet, face, genitalia and airway. In addition, patients often have bouts of excruciating abdominal pain, nausea and vomiting that are caused by swelling in the intestinal wall. 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 infectious and inflammatory 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.

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 ongoing and future preclinical and clinical development of BCX4161 and HAE second generation candidates may not have positive results; that either or both second generation candidates may not advance beyond preclinical development; that BioCryst may not be able to enroll the required number of subjects in the Phase 2a clinical trial of BCX4161; that the Phase 2a trial of BCX4161 may not have a favorable outcome or may not be successfully completed; that the Phase 2a trial may cost more or take longer to complete than expected; that the FDA or similar regulatory agency may refuse to approve subsequent studies, 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 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; 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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