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FDA Grants Fast Track Designation for BCX4161 for the Treatment of Hereditary Angioedema

RESEARCH TRIANGLE PARK, N.C., Jan. 26, 2015 (GLOBE NEWSWIRE) -- [BioCryst Pharmaceuticals, Inc.](#), (Nasdaq:BCRX) today announced that the [U.S. Food and Drug Administration](#) (FDA) has granted Fast Track designation for [BCX4161](#), a novel, orally administered, selective inhibitor of plasma kallikrein in advanced clinical development for the treatment of hereditary angioedema.

The Fast Track designation process of the FDA is designed to facilitate the development and expedite the review and approval of drugs intended to treat serious or life threatening conditions and that address unmet medical needs. A drug that receives Fast Track designation is usually eligible for more frequent written communication and meetings with the FDA to discuss the drug's development plan and the collection of appropriate data supporting drug approval. Priority Review and Rolling Review may be granted, if relevant criteria are met. Rolling Review allows a drug company to submit completed sections of its New Drug Application (NDA) for review by FDA on an ongoing basis, rather than wait until the entire NDA is completed and then reviewed.

"We are very pleased to have been granted orphan drug and fast track status from the FDA, as well as recently receiving a positive opinion for orphan drug designation in Europe," said [Jon P. Stonehouse, President & Chief Executive Officer](#) of BioCryst. "BCX4161 and our second generation molecules have the potential to significantly improve HAE patient treatment and their quality of life. We look forward to reporting results from OPuS-2 and sharing updates regarding BCX7353 and our other second generation HAE assets during 2015."

BioCryst is enrolling HAE patients in the [OPuS-2](#) trial of BCX4161; a double-blind, randomized, placebo controlled trial conducted in the U.S. and certain EU countries, with the goal of demonstrating the efficacy and safety of BCX4161 treatment for 12 weeks in approximately 100 patients with HAE. BioCryst expects to report results from OPuS-2 by the end of 2015.

About BCX4161

Discovered by BioCryst, BCX4161 is a novel, selective inhibitor of plasma kallikrein in development for prevention of attacks in patients with HAE. By inhibiting plasma kallikrein, BCX4161 suppresses bradykinin production. Bradykinin is the mediator of acute swelling attacks in HAE patients. BCX4161 was granted orphan drug status by the FDA and was issued a positive opinion on the application for orphan drug designation for the treatment of patients with HAE by the [Committee for Orphan Medicinal Products](#) (COMP) of the [European Medicines Agency](#) (EMA). BioCryst is also advancing BCX7353 and other second oral kallikrein inhibitors for HAE through preclinical development.

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 the OPuS-2 trial may not have a favorable outcome or may not be successfully completed; that the OPuS-2 trial may cost more or take longer to complete than expected; that regulatory agencies may refuse to approve subsequent HAE studies or delay approval of clinical studies, which may result in a delay of other planned clinical studies and increased development costs of BCX4161; that regulatory agencies may withhold market approval for BCX4161; that ongoing and future preclinical and clinical development of HAE second generation candidates may not have positive results; 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. 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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