



BioCryst Announces Initiation of the APeX-S Long-Term Safety Trial of BCX7353 in Patients with Hereditary Angioedema

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RESEARCH TRIANGLE PARK, N.C., Feb. 28, 2018 (GLOBE NEWSWIRE) -- [BioCryst Pharmaceuticals, Inc.](#) (NASDAQ:BCRX) announced today the dosing of the first patient in APeX-S, a long-term safety trial evaluating two dosage strengths of BCX7353 administered orally once-daily as a preventive treatment in patients with hereditary angioedema (HAE).

HAE is a rare, severely debilitating and potentially fatal genetic condition that causes swelling under the skin in various locations throughout the body, including, at times the throat or airway. Current preventative, or prophylactic, treatment regimens involve multiple injections over time.

"Initiation of the APeX-S trial is an important milestone to support filing and approval of BCX7353, and furthers our core strategy of bringing a once-daily, oral prophylactic treatment to HAE patients," said Jon Stonehouse, Chief Executive Officer. "Long-term safety results from this trial will supplement efficacy and safety data from the APeX-2 Phase 3 trial, which is also expected to commence in the first quarter of 2018. The ability to run these trials concurrently is beneficial, as it may allow us to more rapidly get this important medicine into the hands of patients who are seeking a better quality of life by eliminating their current injection-based treatment programs."

APeX-S is an open label two-arm trial to evaluate the safety of two dose levels of BCX7353 (110 mg once daily and 150 mg once daily) over 48 weeks in patients with Type I and II HAE. The trial will enroll approximately 160 patients. Initially, APeX-S will enroll patients who have participated in a previous clinical trial of BCX7353, and in time will be expanded to include patients who have not previously received the drug. Endpoints of the trial include long-term safety, durability of response and quality of life measures.

"The launch of this trial has brought within arm's reach the fulfillment of the long-standing need of HAE patients for a convenient, easy-to-administer, oral remedy, developed on purpose for the prophylaxis of angioedema attacks," said Henriette Farkas, MD, PhD, DSc and Principal Investigator of the APeX-S trial.

More information on the APeX-S clinical trial will be available on www.clinicaltrials.gov.

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 APeX-S clinical trial evaluating the long-term safety of two dosage strengths of BCX7353 administered orally once-daily as a preventive treatment 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, Japan, Taiwan and Korea. Post-marketing commitments for RAPIVAB are ongoing, as well as activities to support regulatory approvals in other territories. 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 drug candidate may take longer or may be more expensive than planned; that ongoing and future preclinical and clinical development of HAE second generation 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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