



BioCryst Announces Initiation of the Phase 3 APeX-2 Trial of BCX7353 in Patients with Hereditary Angioedema

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RESEARCH TRIANGLE PARK, N.C., March 15, 2018 (GLOBE NEWSWIRE) -- [BioCryst Pharmaceuticals, Inc.](#) (NASDAQ:BCRX) announced today the dosing of the first patient into APeX-2, a Phase 3 clinical trial evaluating two dosage strengths of BCX7353 administered orally once-daily (QD) as a preventive treatment to reduce the frequency of attacks in patients with hereditary angioedema (HAE).

"The ability to safely prevent attacks of angioedema with an oral medicine has been a dream for many HAE patients. Today marks a significant milestone toward the realization of that dream," said Bruce Zuraw, MD and Principal Investigator of the APeX-2 trial. "I am excited to be able to participate in this important trial, which we believe will lead to an effective oral prophylactic treatment offering HAE patients the opportunity to lead a normal life."

APeX-2 is a randomized, double-blind, placebo-controlled, three-arm trial testing two doses of BCX7353 (110 mg and 150 mg) for prevention of angioedema attacks. The trial is expected to enroll approximately 100 patients with Type I and II HAE in the United States, Canada and Europe. The primary efficacy endpoint of APeX-2 is the rate of angioedema attacks over 24 weeks of study drug administration.

"Beginning dosing in the APeX-2 pivotal trial of BCX7353 brings us one step closer to providing a once-daily, oral prophylactic treatment to HAE patients. Our entire organization is encouraged and excited by this important milestone, largely because both physicians and patients have told us they are waiting for a convenient and efficacious HAE treatment that allows patients to lead a more normal life," said Jon Stonehouse, Chief Executive Officer. "We look forward to reporting top-line results from the APeX-2 Phase 3 trial in the first half of 2019."

For more information on the APeX-2 clinical trial, please visit 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 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, 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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