BioCryst Presents Data Highlighting the Rapid and Sustained Plasma Concentrations of BCX7353 in HAE Patients at the Annual Scientific Meeting of the American College of Allergy, Asthma & Immunology

November 16, 2018

RESEARCH TRIANGLE PARK, N.C., Nov. 16, 2018 (GLOBE NEWSWIRE) -- BioCryst Pharmaceuticals, Inc. (Nasdaq:BCRX) today presented data showing that an oral formulation of BCX7353 was rapidly absorbed and exhibited a long half-life, two important characteristics of desired new acute treatments for hereditary angioedema (HAE) attacks, at the Annual Scientific Meeting of the American College of Allergy, Asthma & Immunology (ACAAI) in Seattle.

In the trial, the pharmacokinetic (PK) and kallikrein inhibition profiles of BCX7353 were evaluated for 24 hours post-dose in six subjects with HAE Type I or II who were given a single 750 mg oral dose of BCX7353 in a period between HAE attacks.

The target concentration of BCX7353 that restores plasma kallikrein suppression to normal, or above-normal, levels is ≥ 8x EC_{50}. In the trial, mean concentrations of BCX7353 were approximately 16x EC_{50} within 30 min, and remained at or above this level through at least 24 hours post-dose

“Both rapid onset of action and sustained duration of activity are critical attributes that patients and physicians seek in an improved single-dose oral option for the acute treatment of HAE attacks,” said Dr. William Sheridan, chief medical officer of BioCryst.

“This PK profile supports the clinical benefits that we saw in the placebo-controlled ZENITH-1 clinical trial of a single 750 mg dose of BCX7353 to treat HAE attacks,” Sheridan added.

In order to evaluate prevention of attack progression and symptom relief in the ZENITH-1 trial, study drug (BCX7353 or placebo) was administered early (mean time of administration was 35 minutes) after the onset of symptoms of angioedema, when baseline mean composite visual analog scale (VAS) scores were 14 to 15, on a scale of 0-100.

In ZENITH-1, the VAS scores of subjects receiving a single dose of BCX7353 750 mg were reduced by 6.98 points (p=0.0024) compared to placebo by four hours post-dose, and, through 24 hours, use of standard of care medication to treat HAE attacks was reduced by 31.6 percent after treatment with BCX7353 compared to treatment with placebo (p=0.0029). BCX7353 750 mg single doses were generally safe and well tolerated.

About BioCryst Pharmaceuticals

BioCryst Pharmaceuticals discovers novel, oral small-molecule medicines that treat rare diseases in which significant unmet medical needs exist and an enzyme plays a key role in the biological pathway of the disease. 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 progressiva. 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, Australia, Japan, Taiwan, Korea and the European Union. Post-marketing commitments for RAPIVAB are ongoing. 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 ongoing and future preclinical and clinical development of HAE second generation drug candidates (including ZENITH-1, APeX-2, APeX-S and APeX-J) may not have positive results, may be more expensive or may not move as quickly as planned; that the FDA, EMA or other applicable regulatory agency may not provide regulatory clearances which may result in delay of planned clinical trials or failure to achieve 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.

BCRXW

Contact:
John Bluth
+1 919 859 7910
jbluth@biocryst.com