BioCryst Announces Berotralstat Expanded Access Program for Patients with Hereditary Angioedema in United States

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RESEARCH TRIANGLE PARK, N.C., June 09, 2020 (GLOBE NEWSWIRE) -- BioCryst Pharmaceuticals, Inc. (Nasdaq:BCRX) today announced that the company has established an expanded access program (EAP) with oral, once-daily berotralstat, an investigational drug, for patients with hereditary angioedema (HAE) in the United States.

Through this program, physicians may be able to request berotralstat for HAE patients who do not have access to the product through a clinical trial.

According to the U.S. Food and Drug Administration (FDA), expanded access is a potential pathway for a patient with an immediately life-threatening condition or serious disease or condition to gain access to an investigational medical product for treatment outside of clinical trials when no comparable or satisfactory alternative therapy options are available.

Requests for expanded access to berotralstat must be made by a U.S. licensed physician. Physicians can request access for a patient by sending an email to access.us@inceptua.com or calling 1-888-225-8677.

A new drug application for berotralstat is currently under review by the FDA with an action date of December 3, 2020 under the Prescription Drug User Fee Act (PDUFA).

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 berotralstat (BCX7353), an oral treatment for hereditary angioedema, BCX9930, an oral Factor D inhibitor for the treatment of complement-mediated diseases, galidesivir, a potential treatment for COVID-19, Marburg virus disease and Yellow Fever, and BCX9250, an ALK-2 inhibitor 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 the ongoing COVID-19 pandemic could create challenges in all aspects of our business, including without limitation delays, stoppages, difficulties and increased expenses with respect to our and our partners' development, regulatory processes and supply chains, could negatively impact our ability to access the capital or credit markets to finance our operations, or could have the effect of heightening many of the risks described below or in the documents we file periodically with the Securities and Exchange Commission; that developing any HAE product candidate may take longer or may be more expensive than planned; that ongoing and future preclinical and clinical development of BCX9930, BCX9250 and galidesivir 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 BioCryst may not advance human clinical trials with product candidates as expected; that the FDA, EMA, PMDA 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 candidates, or withhold market approval for product candidates; that actual financial results may not be consistent with expectations, including that 2020 operating expenses and cash usage may not be within management's expected ranges. 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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Contact:
John Bluth
+1 919 859 7910
jbluth@biocryst.com