



## **BioCryst Submits New Drug Application for Oral, Once Daily Berotralstat (BCX7353) to Prevent HAE Attacks**

December 11, 2019

RESEARCH TRIANGLE PARK, N.C., Dec. 11, 2019 (GLOBE NEWSWIRE) -- [BioCryst Pharmaceuticals, Inc.](#) (Nasdaq: BCRX) announced it has submitted a new drug application (NDA) to the U.S. Food and Drug Administration (FDA) for approval of oral, once daily berotralstat (BCX7353) for the prevention of hereditary angioedema (HAE) attacks.

"HAE patients are waiting for a safe, effective oral therapy to manage their disease and this NDA submission brings berotralstat an important step closer to meeting this need for patients and their physicians," said Jon Stonehouse, chief executive officer of BioCryst.

"Thank you to all of the HAE patients who have participated in our clinical trials, to the clinical investigators and their teams around the world who conducted our clinical trials, and to the BioCryst team for always remembering that patients are waiting for our oral, once daily medicine. Our commercial team is hard at work preparing to commercialize berotralstat in 2020," Stonehouse added.

### **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 Marburg virus disease and Yellow Fever, and BCX9250, an ALK-2 inhibitor for the treatment of fibrodysplasia ossificans progressiva. RAPIVAB<sup>®</sup> (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](http://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, performance 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 product candidate may take longer or may be more expensive than planned; that ongoing and future preclinical and clinical development of BCX9930, BCX9250 and 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, 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 candidate, or withhold market approval for product candidates; that actual financial results may not be consistent with expectations, including that 2019 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.

BCRXW

### **Contact:**

John Bluth  
+1 919 859 7910  
[jbluth@biocryst.com](mailto:jbluth@biocryst.com)