BioCryst Appoints Dr. Amy McKee to Board of Directors

September 20, 2021

RESEARCH TRIANGLE PARK, N.C., Sept. 20, 2021 (GLOBE NEWSWIRE) -- BioCryst Pharmaceuticals, Inc. (Nasdaq:BCRX) today announced that the company has appointed regulatory expert and former deputy center director of the U.S. Food and Drug Administration (FDA) Oncology Center of Excellence (OCE), Amy McKee, M.D., to its board of directors.

Dr. McKee currently serves as vice president of regulatory consulting services for Parexel, a leading global clinical research organization. Prior to joining Parexel in 2019, Dr. McKee spent more than a decade at the FDA in leadership roles of increasing responsibility. While there, she applied flexible, evidence-based regulatory approaches to assess novel drugs for serious unmet needs.

Dr. McKee served as a primary reviewer of new drug applications (NDAs) and biologics license applications (BLAs) across multiple divisions and served as both the acting deputy director and supervisory associate director of the Office of Hematology and Oncology products where she managed four separate divisions performing NDA and BLA reviews. From January 2018 through February 2019, Dr. McKee was the deputy center director for the OCE, which helps expedite development of innovative medical products for oncologic and hematologic malignancies and supports an integrated approach to their clinical evaluation.

“At the FDA, we were frequently considering complex drug development programs without regulatory precedent as we worked to advance safe and effective new medicines to patients. I am excited to bring this experience to BioCryst as the company advances BCX9930 into pivotal trials in PNH and other complement-mediated diseases. This R&D team is prolific—they continue to produce new molecules for additional rare diseases and demonstrate innovative thinking in their development programs,” Dr. McKee said.

“Amy's strategic regulatory perspective and substantial FDA experience, especially related to novel approaches to drug development programs to meet serious and unmet needs, represent an exciting addition to the BioCryst board,” said Robert Ingram, chairman of BioCryst.

Dr. McKee received a B.A. in Russian and East European studies from Middlebury College and received her M.D. from Tulane University School of Medicine. She was a clinical fellow at the National Cancer Institute/Johns Hopkins University in the pediatric hematology/oncology fellowship program and is board certified in pediatric hematology/oncology by the American Board of Pediatrics. Dr. McKee has authored more than 30 peer-reviewed articles.

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. Oral, once-daily ORLADEYO® (berotralstat) is approved in the United States, the European Union, Japan, the United Arab Emirates and the United Kingdom. BioCryst has several ongoing development programs including BCX9930, an oral Factor D inhibitor for the treatment of complement-mediated diseases, BCX9250, an ALK-2 inhibitor for the treatment of fibrodysplasia ossificans progressiva, and galidesivir, a potential treatment for Marburg virus disease and Yellow Fever. RAPIVAB® (peramivir injection) has received regulatory approval in the U.S., Canada, Australia, Japan, Taiwan and Korea. 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, 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: the ongoing COVID-19 pandemic, which could create challenges in all aspects of BioCryst’s business, including without limitation delays, stoppages, difficulties and increased expenses with respect to BioCryst’s and its partners’ development, regulatory processes and supply chains, negatively impact BioCryst’s ability to access the capital or credit markets to finance its operations, or have the effect of heightening many of the risks described below or in the documents BioCryst files periodically with the Securities and Exchange Commission; BioCryst’s ability to successfully implement its commercialization plans for, and to commercialize ORLADEYO, which could take longer or be more expensive than planned; the commercial viability of ORLADEYO, including its ability to achieve market acceptance; ongoing and future preclinical and clinical development of BCX9930, BCX9250 and galidesivir may not have positive results; BioCryst may not be able to enroll the required number of subjects in planned clinical trials of product candidates; BioCryst may not advance human clinical trials with product candidates as expected; the FDA, EMA, PMDA or other applicable regulatory agency may require additional studies beyond the studies planned for products and product candidates, may not provide regulatory clearances which may result in delay of planned clinical trials, may impose certain restrictions, warnings, or other requirements on products and product candidates, may impose a clinical hold with respect to product candidates, or may withhold, delay or withdraw market approval for products and product candidates; product candidates, if approved, may not achieve market acceptance; BioCryst’s ability to successfully manage its growth and compete effectively; risks related to the international expansion of BioCryst’s business; and actual financial results may not be consistent with expectations, including that revenue, 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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