MHRA Grants HAE Patients Early Access to BioCryst's Berotralstat in United Kingdom

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RESEARCH TRIANGLE PARK, N.C., Oct. 30, 2020 (GLOBE NEWSWIRE) -- BioCryst Pharmaceuticals, Inc. (Nasdaq: BCRX) today announced that the United Kingdom's Medicines and Healthcare products Regulatory Agency (MHRA) has granted oral, once-daily berotralstat a positive scientific opinion through the Early Access to Medicines Scheme (EAMS).

Under the EAMS, hereditary angioedema (HAE) patients in the UK aged 12 years and older can gain access to berotralstat for the routine prevention of recurrent attacks of HAE before the drug is granted marketing authorization by the European Commission (EC).

HAE is a serious, and potentially life-threatening, rare genetic illness characterised by periodic episodes of acute swelling of the skin, pharynx, larynx, gastrointestinal tract, genitals and/or extremities.

Medicines included in the EAMS are those that have a high unmet need, are intended to treat, diagnose or prevent seriously debilitating or life-threatening conditions where there are no adequate treatment options, and are likely to offer significant advantage over methods currently used in the UK. Under the scheme, the MHRA provides a scientific opinion on the benefit-risk balance of the medicine, based on the data available when the EAMS submission was made.

"There are many patients in the UK that don't have a realistic option for effective HAE prophylaxis. The addition of berotralstat through the EAMS will bring a much needed option for HAE patients suffering with this debilitating disease," said Dr. Sorena Kiani, Consultant Immunologist at Royal London Hospital, London.

"HAE patients around the world are waiting for an oral, once-daily therapy to prevent attacks and reduce their burden of therapy. With this decision by the MHRA, the wait for many HAE patients in the UK can end sooner," said Jon Stonehouse, chief executive officer of BioCryst.

The European Medicines Agency (EMA) is reviewing the marketing authorisation application (MAA) for berotralstat under the centralized procedure. An opinion from the Committee for Medicinal Products for Human Use (CHMP) is expected approximately 12 months from MAA validation, which the company announced on March 30, 2020.

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 ORLADEYO ™ (berotralstat), 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 are identified by use of terms such as "expect," "will," and similar words, although some forward-looking statements may be expressed differently. 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: 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; developing and commercializing ORLADEYO (berotralstat) or any HAE product candidate may take longer or may be more expensive than planned; 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 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 product candidates, may impose a clinical hold with respect to such product candidates, or may withhold market approval for product candidates; product candidates, if approved, may not achieve market acceptance; BioCryst's ability to successfully commercialize its product candidates, 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 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 forward-looking statements.

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