FDA Accepts BioCryst's NDA for Oral, Once Daily Berotralstat (BCX7353) to Prevent HAE Attacks

February 18, 2020

PDUFA date is December 3, 2020

RESEARCH TRIANGLE PARK, N.C., Feb. 18, 2020 (GLOBE NEWSWIRE) -- BioCryst Pharmaceuticals, Inc. (Nasdaq: BCRX) announced that the U.S. Food and Drug Administration (FDA) has accepted and filed its new drug application (NDA) for the approval of oral, once daily berotralstat (BCX7353) for the prevention of hereditary angioedema (HAE) attacks.

The Prescription Drug User Fee Act (PDUFA) date for the NDA is December 3, 2020.

In the NDA filing acceptance letter, the FDA stated that they are not currently planning to hold an advisory committee meeting to discuss the NDA.

"HAE patients and their physicians tell us they have been waiting for a once daily oral therapy to prevent attacks, and the acceptance of our submission, with a PDUFA date this year, means their wait is nearly over," said Jon Stonehouse, chief executive officer of BioCryst. "We are sharply focused on building out a very experienced commercial team and executing our commercial plan, so we are ready to go fast when we get approval."

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® (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, 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 the FDA, PMDA, EMA or other applicable regulatory agency may not approve berotralstat, within the timeframe expected, or at all, may ultimately determine that there are deficiencies in the development program or execution thereof, may require additional information or studies, may disagree with our analyses regarding the safety and efficacy conclusions; in the future they could determine that an advisory committee is necessary; we may learn of previously unknown issues; ongoing studies may take longer or may be more expensive than planned; in the event that berotralstat is approved in any territory, we or our partners may be unable to successfully commercialize as expected; that actual financial results may not be consistent with expectations, including that 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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