European Medicines Agency Validates Marketing Authorization Application for Oral, Once-Daily Berotralstat (BCX7353) to Prevent HAE Attacks

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RESEARCH TRIANGLE PARK, N.C., March 30, 2020 (GLOBE NEWSWIRE) -- BioCryst Pharmaceuticals, Inc. (Nasdaq: BCRX) announced that the European Medicines Agency (EMA) has validated its marketing authorization application (MAA) submission for approval of oral, once-daily berotralstat (BCX7353) for the prevention of hereditary angioedema (HAE) attacks.

With this validation, the EMA has begun their formal review of the MAA under the centralized procedure for all member states of the European Union, and Norway, Iceland and Liechtenstein.

An opinion from the Committee for Medicinal Products for Human Use (CHMP) is expected within approximately 12 months.

“Berotralstat would represent the first targeted oral therapy approved for HAE prophylaxis in Europe and would deliver a major advance in therapy to HAE patients,” said Jon Stonehouse, chief executive officer of BioCryst.

“HAE treatment in Europe tends to be consolidated and we have developed excellent relationships with HAE-treating physicians through our clinical trials. This is allowing us to build an efficient and experienced European commercial team to bring our innovative medicine to patients,” Stonehouse added.

BioCryst expects three regulatory approvals for berotralstat in 2020 and early 2021. The U.S. Food and Drug Administration (FDA) is currently reviewing a new drug application for berotralstat and has set an action date of December 3, 2020 under the Prescription Drug User Fee Act (PDUFA). In Japan, the Pharmaceuticals and Medical Devices Agency (PMDA) is reviewing a new drug application (JNDA) for berotralstat under the Sakigake timeline, and the company expects Japanese approval in the second half of 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 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 developing any HAE product candidate may take longer or may be more expensive than planned; that ongoing and future preclinical and clinical studies 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 decisions or processes may be negatively impacted by the COVID-19 pandemic; that such agencies 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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