

New Composition of Matter Patent Allowance Extends Protection for Berotralstat in U.S. Market by Four Years to 2039

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RESEARCH TRIANGLE PARK, N.C., May 05, 2020 (GLOBE NEWSWIRE) -- BioCryst Pharmaceuticals, Inc. (Nasdaq:BCRX) today announced that the United States Patent and Trademark Office (USPTO) has issued a notice of allowance for patent application 16/671,649. The resulting U.S. patent, once issued, will extend the patent protection for berotralstat (BCX7353) in the United States by four years through October 2039.

The allowed patent application covers crystalline salt forms of berotralstat active pharmaceutical ingredient (API).

"The extension of U.S. patent protection for berotralstat, through 2039, adds significant value to BioCryst. We look forward to the U.S. approval and launch of oral, once-daily berotralstat later this year," said Jon Stonehouse, chief executive officer of BioCryst.

The U.S. Food and Drug Administration is reviewing a new drug application (NDA) for approval of oral, once-daily berotralstat for the prevention of hereditary angioedema attacks. The Prescription Drug User Fee Act (PDUFA) date for the NDA is December 3, 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 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 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: that the ongoing COVID-19 pandemic could create challenges in all aspects of our business, including without limitation delays, stoppages, difficulties and increased expenses with respect to our and our partners' development, regulatory processes and supply chains, could negatively impact our ability to access the capital or credit markets to finance our operations, or could have the effect of heightening many of the risks described below or in the documents we file periodically with the Securities and Exchange Commission; 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 galidesivir 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 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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