BioCryst Announces Acceptance and Accelerated Review of the ORLADEYO™ (berotralstat) Marketing Application by the Israeli Ministry of Health

June 16, 2021

— Neopharm Ltd. selected as exclusive distribution and supply partner of ORLADEYO in Israel —

RESEARCH TRIANGLE PARK, N.C., June 16, 2021 (GLOBE NEWSWIRE) -- BioCryst Pharmaceuticals, Inc. (Nasdaq: BCRX) today announced that the Israeli Ministry of Health has accepted the regulatory submission of ORLADEYO for the prevention of recurrent attacks in patients with hereditary angioedema (HAE) 12 years and older. The Israeli Ministry of Health also has granted an accelerated review. In addition, BioCryst has entered into a distribution and supply agreement granting Neopharm Ltd., a corporation organized under the laws of the State of Israel, the exclusive rights to commercialize ORLADEYO in Israel.

“Neopharm is the right partner to help us commercialize in Israel as we continue to bring oral, once-daily ORLADEYO to HAE patients around the world. They have extensive rare disease experience and proven commercial success in Israel, and they understand the local regulatory environment,” said Charlie Gayer, chief commercial officer of BioCryst.

“We are proud of our partnership with BioCryst and excited to deliver a new and innovative treatment option to HAE patients in Israel. The momentum gained from recent approvals of ORLADEYO across the globe will support our commercialization efforts to provide access to this important treatment,” said Efi Shnaidman, general manager of Neopharm Israel.

Founded in 1941, Neopharm Israel is one of the leading pharmaceutical companies in Israel, providing the Israeli market with a wide range of products and integrated services for patients in need, with a proven track record of successful market access and launches. In addition to exclusive rights to commercialize ORLADEYO in Israel, Neopharm Israel has exclusive rights to commercialize in the Palestinian Authority.

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 and the United Kingdom for the prevention of HAE attacks in adults and pediatric patients 12 years and older. 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), a viral neuraminidase inhibitor for the treatment of influenza, 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 BioCryst’s plans and expectations for ORLADEYO. These statements involve known and unknown risks, uncertainties and other factors which may cause 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 periodically files 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; the results of our partnership with Neopharm may not meet our current expectations; the FDA, Israeli Ministry of Health 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; 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 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, 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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