BioCryst and the pan-Canadian Pharmaceutical Alliance (pCPA) Successfully Complete Negotiations for ORLADEYO® (berotralstat), an Oral, Once-daily Therapy for the Prevention of Hereditary Angioedema Attacks

September 17, 2024 07:00 ET | Source: BioCryst Pharmaceuticals, Inc.

INTENDED FOR CANADIAN AUDIENCES ONLY

TORONTO, Sept. 17, 2024 (GLOBE NEWSWIRE) -- BioCryst Pharmaceuticals, Inc. (Nasdaq: BCRX) today announced that it successfully completed negotiations with the pan-Canadian Pharmaceutical Alliance (pCPA) for oral, once-daily PrORLADEYO® (berotralstat), which is approved in Canada for the routine prevention of attacks of hereditary angioedema (HAE) in adults and pediatric patients 12 years of age and older.

"Providing access to a range of therapies and alternative drug administration methods is crucial for enabling patients to self-manage their HAE, achieve optimal health and live attack-free lives. Today's announcement marks an important step in making ORLADEYO accessible through our publicly funded healthcare system for many people across Canada living with HAE. We appreciate the collaboration between BioCryst and the pCPA to reach this agreement to help improve the quality of life for HAE patients," said Michelle Cooper, president of HAE Canada.

"The completion of the negotiations with pCPA mark a critical step in bringing ORLADEYO to patients with HAE through the public health system in Canada. In a relatively short amount of time, we have made significant progress, including securing approval of ORLADEYO from Health Canada and receiving positive recommendations from Canada's Drug Agency and INESSS. These achievements fuel our mission to bring our oral, once-daily prophylactic therapy to as many people living with HAE as possible around the world," said Anand Janack, vice president and general manager of BioCryst Canada.

While some Canadian patients with HAE are eligible to receive reimbursement for ORLADEYO through private health insurance plans, BioCryst will now partner with the individual public drug plans of provinces and territories to ensure that ORLADEYO is added to public formularies. This will enable people with HAE in Canada who might benefit from treatment with ORLADEYO to access the therapy.

ORLADEYO was approved by Health Canada in June 2022. Subsequently, BioCryst received positive recommendations for ORLADEYO from Canada's Drug Agency (CDA; formerly CADTH) and the Institut national d'excellence en santé et services sociaux (INESSS) in March 2023 and September 2023, respectively. BioCryst and pCPA entered into negotiations for the reimbursement of ORLADEYO in early 2024.

About PrORLADEYO® (berotralstat)
PrORLADEYO® (berotralstat) is an oral therapy designed specifically to prevent attacks of hereditary angioedema (HAE) in adult and pediatric patients 12 years and older. One capsule of ORLADEYO per day works to prevent HAE attacks by decreasing the activity of plasma kallikrein.

INDICATION
PrORLADEYO® (berotralstat) is indicated for the routine prevention of attacks of hereditary angioedema (HAE) in adults and pediatric patients 12 years of age and older.

LIMITATIONS OF USE
The safety and effectiveness of ORLADEYO for the treatment of acute HAE attacks have not been established. ORLADEYO should not be used for the treatment of acute HAE attacks. Additional doses or dosages of ORLADEYO higher than 150 mg once daily are not recommended due to the potential for QT prolongation.

IMPORTANT SAFETY INFORMATION
The overall safety of ORLADEYO has been evaluated in multiple long-term clinical studies, which included 381 patients with HAE (uncontrolled, open-label and placebo-controlled, blinded studies).

Of the patients treated with ORLADEYO in the placebo-controlled blinded Phase 3 study (Study 302, Part 1), the most common adverse reactions associated with ORLADEYO 150 mg were gastrointestinal reactions, which included abdominal pain in any location (23%), vomiting (15%), and diarrhea (15%). These reactions generally occurred early after initiation of treatment with ORLADEYO, became less frequent with time, and typically self-resolved. No patients in the ORLADEYO 150 mg dose group discontinued treatment due to a gastrointestinal adverse reaction. There were no serious drug-related treatment-emergent adverse events in patients who received ORLADEYO.

Patients with moderate or severe hepatic impairment may develop increased serum berotralstat concentrations. Use of ORLADEYO in these patients should be avoided.

ORLADEYO is a P-glycoprotein (P-gp) and breast cancer resistance protein (BCRP) substrate. ORLADEYO exposure may be increased with concomitant administration of P-gp and BCRP inhibitors, but no dose adjustment is necessary. Close monitoring for adverse events is recommended for concomitant use with P-gp and BCRP inhibitors. P-gp and BCRP inducers (e.g., rifampicin, St. John's wort) may decrease berotralstat plasma concentration, leading to reduced efficacy of berotralstat. The use of P-gp inducers is not recommended with ORLADEYO.

ORLADEYO at a once-daily dose of 150 mg is a moderate inhibitor of CYP2D6 and CYP3A4. For concomitant medications with a narrow therapeutic index that are predominantly metabolized by CYP2D6 or CYP3A4, appropriate monitoring and dose adjustment of these medications may be required.

The safety and effectiveness of ORLADEYO in pediatric patients <12 years of age have not been established.

There are insufficient data available to inform drug-related risks with ORLADEYO use in pregnancy. There are no data on the presence of berotralstat in human milk, its effects on the breastfed infant, or its effects on milk production. There are no data on the influence of ORLADEYO use on human fertility.

The frequent side effects include: abdominal discomfort; vomiting; diarrhea; back pain; headache; heartburn; gas; rash; liver function test elevations (shown in blood tests).

You can report any suspected side effects associated with the use of health products to Health Canada by:

Visiting the Web page on Adverse Reaction Reporting (https://www.canada.ca/en/health-canada/services/drugs-health-products/medeffect-canada/adverse-reaction-reporting.html) for information on how to report online, by mail or by fax; or:
Calling toll-free at 1-866-234-2345
Please see full Product Monograph.

About BioCryst Pharmaceuticals
BioCryst Pharmaceuticals is a global biotechnology company with a deep commitment to improving the lives of people living with complement-mediated and other rare diseases. BioCryst leverages its expertise in structure-guided drug design to develop first-in-class or best-in-class oral small-molecule and protein therapeutics to target difficult-to-treat diseases. BioCryst has commercialized PrORLADEYO® (berotralstat), the first oral, once-daily plasma kallikrein inhibitor, and is advancing a pipeline of small-molecule and protein therapies. For more information, please visit www.biocryst.com or follow us on LinkedIn.

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: BioCryst's ability to successfully implement or maintain its commercialization plans for ORLADEYO; the results of BioCryst's partnerships with third parties may not meet BioCryst's current expectations; risks related to government actions, including that decisions and other actions, including as they relate to pricing, may not be taken when expected or at all, or that the outcomes of such decisions and other actions may not be in line with BioCryst's current expectations; the commercial viability of ORLADEYO, including its ability to achieve sustained market acceptance; the FDA 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 revenue, 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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