



## BioCryst to Present New ORLADEYO® (berotralstat) Data at 2023 American Academy of Allergy, Asthma & Immunology Annual Meeting

February 3, 2023

RESEARCH TRIANGLE PARK, N.C., Feb. 03, 2023 (GLOBE NEWSWIRE) -- [BioCryst Pharmaceuticals, Inc.](#) (Nasdaq: BCRX) today announced that the company will present four abstracts featuring data on oral, once-daily ORLADEYO® (berotralstat) for the prophylactic treatment of hereditary angioedema (HAE) at the 2023 American Academy of Allergy, Asthma & Immunology (AAAAI) annual meeting, which is being held in San Antonio, Texas, from February 24-27, 2023.

"We continue to build a consistent library of evidence that showcases the value of ORLADEYO through a combination of new analyses from our long-term clinical program and real-world evidence," said Dr. Ryan Arnold, chief medical officer of BioCryst. "From new real-world evidence that further demonstrates a meaningful reduction in attack rates experienced by patients who are on ORLADEYO, to additional analyses detailing sustained improvements in patient-reported QoL, the findings that we will present at AAAAI continue to show that our oral, once-daily prophylactic therapy is making a difference for many patients living with HAE."

The four abstracts that BioCryst will present are:

- *Disease and Treatment Burden of Hereditary Angioedema (HAE) in Pediatric Patients: Assessment by Caregivers*; Poster #417; Sunday, February 26, 9:45-10:45 am CT
- *Long-term HAE Prophylaxis with Berotralstat Is Well Tolerated and Effective: Analysis for the APeX-S Study*; Poster #398; Sunday, February 26, 9:45-10:45 am CT
- *Berotralstat Improved Quality of Life through 96 Weeks Across Multiple Subgroups of Patients with Hereditary Angioedema*; Poster #426; Sunday, February 26, 9:45-10:45 am CT
- *Real-World Outcomes in Patients with Hereditary Angioedema (HAE) Treated with Berotralstat*; Poster #415; Sunday, February 26, 9:45-10:45 am CT

The abstracts are now available to view in an online supplement to *The Journal of Allergy and Clinical Immunology* (JACI) at [jacionline.org](#).

### About ORLADEYO® (berotralstat)

ORLADEYO® (berotralstat) is the first and only 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.

### U.S. Indication and Important Safety Information

#### INDICATION

ORLADEYO® (berotralstat) is a plasma kallikrein inhibitor indicated for prophylaxis to prevent attacks of hereditary angioedema (HAE) in adults and pediatric patients 12 years 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

An increase in QT prolongation was observed at dosages higher than the recommended 150 mg once-daily dosage and was concentration dependent.

The most common adverse reactions ( $\geq 10\%$  and higher than placebo) in patients receiving ORLADEYO were abdominal pain, vomiting, diarrhea, back pain, and gastroesophageal reflux disease.

A reduced dosage of 110 mg taken orally once daily with food is recommended in patients with moderate or severe hepatic impairment (Child-Pugh B or C) and in patients taking chronically administered P-glycoprotein (P-gp) or breast cancer resistance protein (BCRP) inhibitors (eg, cyclosporine).

Berotralstat is a substrate of P-gp and BCRP. P-gp inducers (eg, rifampin, St. John's wort) may decrease berotralstat plasma concentration, leading to reduced efficacy of ORLADEYO. The use of P-gp inducers is not recommended with ORLADEYO.

ORLADEYO at a 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 titration is recommended. ORLADEYO at a dose of 300 mg

is a P-gp inhibitor. Appropriate monitoring and dose titration is recommended for P-gp substrates (eg, digoxin) when coadministering with ORLADEYO.

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.

**To report SUSPECTED ADVERSE REACTIONS, contact BioCryst Pharmaceuticals, Inc. at 1-833-633-2279 or FDA at 1-800-FDA-1088 or [www.fda.gov/medwatch](http://www.fda.gov/medwatch).**

**Please see full [Prescribing Information](#).**

#### **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 and many global markets. BioCryst has active programs to develop oral medicines for multiple targets across the complement system, including BCX10013, an oral Factor D inhibitor in clinical development. RAPIVAB® (peramivir injection) is approved in the U.S. and multiple global markets, with post-marketing commitments ongoing. For more information, please visit the company's website at [www.biocryst.com](http://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 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 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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#### **Investor Contact:**

John Bluth  
+1 919 859 7910  
[jbluth@biocryst.com](mailto:jbluth@biocryst.com)

#### **Media Contact:**

Catherine Collier Kyroulis  
+1 917 886 5586  
[ckyroulis@biocryst.com](mailto:ckyroulis@biocryst.com)