



## BioCryst to Present New Data at 2025 Meeting of the European Academy of Allergy and Clinical Immunology

June 2, 2025

RESEARCH TRIANGLE PARK, N.C., June 02, 2025 (GLOBE NEWSWIRE) -- [BioCryst Pharmaceuticals, Inc.](#) (Nasdaq: BCRX) today announced that new data on oral, once-daily ORLADEYO® (berotralstat) for the prophylactic treatment of hereditary angioedema (HAE) will be presented at the European Academy of Allergy and Clinical Immunology (EAACI) meeting in Glasgow, United Kingdom, from June 13 to 16, 2025.

BioCryst will present four abstracts at the meeting:

**Impact of Berotralstat on Quality of Life among Patients with Hereditary Angioedema: Pooled Analysis of the APeX-2 and APeX-J Trials.** Session #TPS40, poster #D2.329, poster zone, Saturday, June 14, 2025, from 12:00-13:00 (BST).

**Patients with HAE Report Positive Perceptions Following Berotralstat Treatment: Results from a Focus Group.** Session #TPS40, poster #D2.332, poster zone, Saturday, June 14, 2025, from 12:00-13:00 (BST).

**Assessment of the Effectiveness and Tolerability of Berotralstat for Long-term Prophylaxis in Hereditary Angioedema: Findings from the Berolife Study.** Session #FT16, Dochart 1 room, Sunday, June 15, from 14:14 to 14:21 (BST).

**Berotralstat Use Reduced Number of HAE Attacks Requiring Treatment or Professional Care in Pediatric Patients: Interim Results from APeX-P.** Session #FT16, Dochart 1 room, Sunday, June 15, 2025, from 14:35 to 14:42 (BST).

### 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 (≥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).

Berotralstat is a substrate of P-glycoprotein (P-gp) and breast cancer resistance protein. 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 is a global biotechnology company with a deep commitment to improving the lives of people living with hereditary angioedema and other rare diseases. BioCryst leverages its expertise in structure-guided drug design to develop first-in-class or best-in-class small-molecule and protein therapeutics to target difficult-to-treat diseases. BioCryst has commercialized ORLADEYO® (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](http://www.biocryst.com) or follow us on [LinkedIn](#).

## **Forward-Looking Statements**

This press release contains forward-looking statements, including statements regarding future results, performance or achievements and statements relating to ORLADEYO performance and effectiveness. 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 outcome of early clinical trials may not be predictive of the success of later clinical trials, and interim results of a clinical trial do not necessarily predict final results; 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; and BioCryst's ability to successfully manage its growth and compete effectively. 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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