BioCryst Presents New Real-World Evidence Showing Reduced Angioedema-Related Medical Visits After Switching to ORLADEYO® (berotralstat) at ACAAI 2026 Annual Scientific Meeting

November 13, 2026

—Two real-world studies demonstrate reductions in healthcare resource utilization in HAE patients who initiated or switched to ORLADEYO® from another prophylactic therapy —

RESEARCH TRIANGLE PARK, N.C., Nov. 13, 2026 (GLOBE NEWSWIRE) -- BioCryst Pharmaceuticals, Inc. (Nasdaq: BCRX) today announced new real-world evidence on the use of once-daily ORLADEYO® (berotralstat), the first and only targeted oral prophylactic therapy for patients with hereditary angioedema (HAE) aged 2 and older, showing reductions in hospitalizations and emergency department visits following ORLADEYO initiation in patients new to long-term prophylactic therapy (LTP) and in patients switching to ORLADEYO from another LTP.

This practice-informing research will be featured across two poster presentations during the American College of Allergy, Asthma & Immunology (ACAAI) 2026 Annual Scientific Meeting taking place in Phoenix, Arizona, November 12-16.

“These real-world studies add to our understanding of healthcare resource utilization among patients with HAE who either initiate ORLADEYO or switch from another long-term prophylactic therapy,” said Sandra Christiansen, MD, professor of medicine and director of translational research at the US HAEA Angioedema Center at the University of California, San Diego. “Patients initiating long-term prophylaxis were found to have comparable reductions in hospitalizations and emergency department visits for ORLADEYO, lanadelumab and subcutaneous plasma-derived C1-inhibitor. Patients who switched to ORLADEYO from an alternative first-line long-term prophylactic therapy experienced a decrease in their angioedema-related medical visits. Taken together, these findings support ORLADEYO’s clinical and economic benefits as a long-term prophylactic therapy for HAE.”

A poster titled ***Reductions in Healthcare Utilization Among Individuals with HAE Who Switched to Berotralstat from Another Prophylaxis*** (Poster #R096) details findings from a retrospective pre-post study that featured analysis of administrative claims data of patients with HAE in the United States linked with proprietary data from the ORLADEYO patient base through BioCryst’s sole source specialty pharmacy. The analysis focused on individuals aged ≥12 years with HAE who switched from another LTP to ORLADEYO who had a baseline of at least six months of continuous insurance plan eligibility prior to starting ORLADEYO (n=78).

Patients with HAE who switched from another LTP to ORLADEYO experienced significant reductions in angioedema-related healthcare resource utilization. All statistical tests were two-sided, with an alpha level of 0.05. Results with $p<0.05$ were considered statistically significant:

- Overall angioedema-related visits decreased significantly by 30% per-patient-year (PPY) (p=0.039, sig)
- Rates of angioedema-related outpatient/emergency department visits decreased significantly by 30% PPY (p=0.040, sig)
- Rates of angioedema-related hospitalizations decreased to 0.12 PPY post-index (rate ratio [95% CI]: 0.54 [0.21–1.39], non-significant)

This poster will be on display in the expo hall of the Phoenix Convention Center and will be presented on Saturday, November 14, 11:30-11:45 a.m. MT.

A second poster titled ***Hospitalization and Emergency Department Reductions After Initiating Berotralstat, Lanadelumab, or Subcutaneous Plasma-Derived C1-Inhibitor for Hereditary Angioedema*** (Poster #R077) reported findings from a retrospective observational pre-post cohort study of all-cause and angioedema-related hospitalization and emergency department visits. The assessment focused on LTP treatment naïve patients aged ≥12 years who initiated treatment with ORLADEYO (n=128), lanadelumab (n=236) or subcutaneous plasma-derived C1-inhibitor (SC-pdC1-INH) (n=95) between June 2017 and October 2024 with ≥6 months of continuous insurance enrollment and evidence of HAE prior to LTP treatment initiation.

All cohorts experienced statistically significant reductions in emergency department visits and reductions were also observed in hospitalizations:

- Reductions in all-cause hospitalization ranged from -26% (SC-pdC1-INH cohort) to -53% (ORLADEYO cohort)
- Reductions in all-cause emergency department visits ranged from -34% (SC-pdC1-INH cohort) to -48% (lanadelumab cohort)
- Reductions in angioedema-related hospitalization ranged from -46% (SC-pdC1-INH cohort) to -59% (lanadelumab cohort)
- Reductions in angioedema-related emergency department visits ranged from -43% (SC-pdC1-INH cohort) to -61% (ORLADEYO cohort)
- No statistically significant differences in magnitude of reductions were observed between ORLADEYO and lanadelumab or SC-pdC1-INH

This poster will be on display in the expo hall of the Phoenix Convention Center and will be presented on Friday, November 13, 4:20-4:35 p.m. MT.

In addition to these real-world studies, BioCryst will also present new clinical data from its HAE portfolio designed to support diverse patient needs and preferences at the ACAAI 2026 Annual Scientific Meeting, including:

- ***Growth-Related Berotralstat Dose Adjustment in Children with Hereditary Angioedema: 48-Week Dosing Experience from APeX-P;*** Poster #R097; Monitor 15; Saturday, November 14, 11:45 a.m.-12:00 p.m. MT
- ***Long-Term Safety, Efficacy, and Quality of Life with Navenibart in Hereditary Angioedema: ALPHA-SOLAR Interim Results;*** Poster #R110; Monitor 13; Sunday, November 15, 12:00-12:15 p.m. MT

Visit www.ORLADEYO.com for more information.

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 2 years and older. One dose 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 2 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 doses of ORLADEYO higher than the prescribed once-daily dose are not recommended due to the potential for QTc interval prolongation.

IMPORTANT SAFETY INFORMATION
An increase in QTc interval was observed in adults at dosages higher than 150 mg once daily and was concentration dependent.

The most common adverse reactions (≥10%) in patients receiving ORLADEYO were abdominal pain, vomiting, diarrhea, back pain and gastroesophageal reflux disease.

In adult and pediatric patients aged 12 years and older with moderate or severe hepatic impairment (Child-Pugh B or C), the recommended dosage of ORLADEYO capsules is 110 mg once daily with food. In pediatric patients aged 2 to <12 years with moderate or severe hepatic impairment (Child-Pugh B or C), avoid use of ORLADEYO.

Berotralstat is a substrate of P-glycoprotein (P-gp) and breast cancer resistance protein. P-gp inducers may decrease berotralstat plasma concentration, leading to reduced efficacy of ORLADEYO. Avoid concomitant use of P-gp inducers with ORLADEYO.

ORLADEYO at a dose of 150 mg is a moderate inhibitor of CYP2D6 and CYP3A4. Concomitant use of ORLADEYO with CYP2D6 or CYP3A4 substrates can increase exposure of the CYP2D6 or CYP3A4 substrates and may increase the risk of adverse reactions associated with the substrates. If ORLADEYO is concomitantly used with CYP2D6 or CYP3A4 substrates where minimal increases in the concentration of the substrates may lead to serious adverse reactions, closely monitor or modify the dosage of the CYP2D6 or CYP3A4 substrate.

The safety and effectiveness of ORLADEYO in pediatric patients <2 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.

About navenibart
Navenibart is an investigational YTE-modified monoclonal antibody inhibitor of plasma kallikrein, an established and safe mechanism, currently being evaluated in clinical trials for long-term prevention of HAE attacks with potential best-in-class dosing every 3 or 6 months.

About BioCryst Pharmaceuticals
BioCryst is a global biotechnology company focused on developing and commercializing medicines for hereditary angioedema ("HAE") and other rare diseases, driven by its deep commitment to improving the lives of people living with these conditions. BioCryst has commercialized ORLADEYO® (berotralstat), the first oral, once-daily plasma kallikrein inhibitor and is advancing a pipeline of potential first-in-class or best-in-class therapeutics for rare diseases. 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 the clinical and economic benefits of ORLADEYO and the development, potential dosing profile, competitive positioning, and expectations for navenibart. 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: risks related to the development and interpretation of real-world data; BioCryst's ability to successfully implement or maintain its commercialization plans for ORLADEYO; BioCryst's ability to successfully progress its development plans for navenibart; the outcome of preclinical testing and 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; ongoing and future clinical development of product candidates, including navenibart, may take longer than expected and may not have positive results; BioCryst may not advance human clinical trials with product candidates, including navenibart, as expected; the FDA or other applicable regulatory agencies 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 not review regulatory filings on our expected timeline, 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, may ultimately determine that there are deficiencies in the development program or execution

thereof, may require additional information or studies, may disagree with our safety and efficacy conclusions, or may impose certain restrictions, warnings, or other requirements; product candidates, if approved, may not achieve market acceptance; and BioCryst's ability to successfully commercialize its products and product candidates. This list is not exclusive. To see a more comprehensive set of risks, 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 actual results to differ materially from those contained in BioCryst's forward-looking statements.

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