



February 8, 2016

BioCryst Announces Results From OPuS-2

RESEARCH TRIANGLE PARK, N.C., Feb. 08, 2016 (GLOBE NEWSWIRE) -- [BioCryst Pharmaceuticals, Inc.](#), (NASDAQ:BCRX) today announced results from [OPuS-2](#) (Oral Prophylaxis-2), a clinical trial of [avoralstat](#) administered three times daily as a liquid-filled soft gel formulation for the prophylactic treatment of hereditary angioedema (HAE) attacks.

In the OPuS-2 study, HAE patients with a historical attack frequency of greater than 0.45 attacks per week were randomized to treatment with either 500 mg or 300 mg of avoralstat, or placebo, administered three times daily for 12 weeks. The primary goals of the trial were to characterize the efficacy of avoralstat in reducing the frequency of angioedema attacks, and to evaluate the safety and tolerability of 12 weeks of avoralstat treatment. The primary efficacy endpoint was angioedema attack frequency.

Thirty-eight subjects received avoralstat 500 mg, 36 subjects received avoralstat 300 mg, and 36 subjects received placebo. Treatment with 500 mg and 300 mg of avoralstat three times daily failed to demonstrate a statistically significantly lower mean attack rate versus placebo. The mean (standard deviation) attack rates per week were 0.63 (0.57) on avoralstat 500mg, 0.71 (0.66) on avoralstat 300mg, compared to 0.61 (0.41) on placebo.

"OPuS-2 was a well-designed and executed trial that gave us a clear answer; this dosage form of avoralstat is not a viable formulation to move forward," said [Jon P. Stonehouse, President & Chief Executive Officer](#). "While we are disappointed in the study results, we learned that meaningfully better exposure is needed for avoralstat to succeed. We expect results from a relative bioavailability study testing a novel solid dosage form of avoralstat by mid-year - the primary goals of this study are to achieve much higher exposures and twice daily dosing. Our other opportunity to achieve higher exposure of an oral kallikrein inhibitor is with BCX7353 - we expect results from the BCX7353 APeX-1 dose ranging study in HAE patients by year end."

Secondary efficacy endpoints included measures of quality of life, attack duration and attack severity. Statistically significant improvements in duration of attacks and in the Angioedema Quality of Life total score, and its domains, were observed comparing the 500 mg three times a day avoralstat arm to placebo.

Oral administration of avoralstat in OPuS-2 was generally safe and well tolerated; the adverse event profile was similar to that for placebo; and no safety signals were observed.

Conference Call and Web Cast

BioCryst's management team will host a conference call and webcast today, February 8, 2016 at 8:00 a.m. Eastern Time, to discuss the results of the OPuS-2 trial and other aspects of BioCryst's HAE development program. To participate in the conference call, please dial 1-877-303-8027 (United States) or 1-760-536-5165 (International). No passcode is needed for the call. The webcast can be accessed by logging onto <http://www.biocryst.com>. Please connect to the web site at least 15 minutes prior to the start of the conference call to ensure adequate time for any software download that may be necessary.

About Avoralstat

Discovered by BioCryst, avoralstat is a novel, selective inhibitor of plasma kallikrein in development for prevention of attacks in patients with hereditary angioedema (HAE). By inhibiting plasma kallikrein, Avoralstat suppresses bradykinin production. Bradykinin is the mediator of acute swelling attacks in HAE patients.

About Hereditary Angioedema

HAE is a rare, severely debilitating and potentially fatal genetic condition that occurs in about 1 in 10,000 to 1 in 50,000 people. HAE symptoms include recurrent episodes of edema in various locations, including the hands, feet, face, genitalia and airway. In addition, patients often have bouts of excruciating abdominal pain, nausea and vomiting that are caused by swelling in the intestinal wall. Airway swelling is particularly dangerous and can lead to death by asphyxiation. Further information regarding HAE can be found at www.haea.org.

About BioCryst Pharmaceuticals

BioCryst Pharmaceuticals designs, optimizes and develops novel small molecule drugs that block key enzymes involved in rare diseases. BioCryst's ongoing development programs include oral plasma kallikrein inhibitors for hereditary angioedema; [avoralstat](#), BCX7353 and other second generation compounds, and [BCX4430](#), a broad spectrum viral RNA polymerase inhibitor. 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 future results, performance or achievements. These statements involve known and unknown risks, uncertainties and other factors which may cause BioCryst's actual results, performance or achievements to be materially different from any future results, performances 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 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: that regulatory determinations regarding the requirements for pre-clinical and clinical studies (including, toxicology, carcinogenicity or long-term safety studies) may negatively impact planned filing for market approval of avoralstat and BCX7353 and may also increase development costs; that the FDA may withhold market approval for avoralstat and BCX7353. That development of the novel solid dosage form of avoralstat may not achieve twice daily dosing at desired drug exposure levels. That APeX-1 may not be successfully completed or APeX-1 may not result in a positive clinical outcome. 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, all of which identify important factors that could cause the actual results to differ materially from those contained in BioCryst's projections and forward-looking statements.

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