BioCryst Pharmaceuticals Presents New BCX4208 Gout Data at the 2011 ACR/ARHP Annual Scientific Meeting

BioCryst to host a conference call & webcast today at 7:45 p.m. Central Time

RESEARCH TRIANGLE PARK, N.C.--(BUSINESS WIRE)-- BioCryst Pharmaceuticals, Inc. (NASDAQ:BCRX) presents new results today from its Phase 2b randomized, double-blind, dose-response study of BCX4208 in patients with gout who have failed to reach the clinically important serum uric acid (sUA) goal of <6 mg/dL on allopurinol alone. The results were accepted as a late-breaking oral presentation titled "BCX4208 Combined With Allopurinol Increases Response Rates in Patients With Gout Who Fail to Reach Goal Range Serum Urate on Allopurinol Alone: A Randomized, Double-Blind, Placebo-Controlled Trial" at the 2011 American College of Rheumatology and the Association of Rheumatology Health Professionals (ACR/ARHP) Annual Scientific Meeting. The presentation will take place today from 2:30-4:30 p.m. Central Time (Presentation Number L10; W375c (McCormick Place West)).

This Phase 2b study randomized 279 patients to five study arms: BCX4208 at doses of 5 mg, 10 mg, 20 mg, 40 mg and placebo, administered once-daily for 12-weeks. Allopurinol 300 mg once-daily was administered in all study arms. The primary study endpoint was the proportion of patients with sUA <6 mg/dL at day 85. The mean baseline sUA for the randomized population was 6.9 mg/dL.

The primary endpoint of the study was successfully achieved. When added to allopurinol 300 mg, BCX4208 was superior to allopurinol plus placebo (p=0.009 overall). BCX4208 doses evaluated in the study showed response rates ranging from 33% to 49%, approximately doubling the proportion of patients reaching goal on placebo (18%). BCX4208 added to allopurinol was generally safe and well-tolerated at all doses studied.

"This important study demonstrates that low doses of BCX4208 combined with allopurinol safely and significantly increase the proportion of patients reaching therapeutic goal compared to 300 mg allopurinol, the most commonly prescribed dose in the U.S. The study population was representative of the general gout population, and included patients with mild renal impairment, kidney stones and other co-morbidities," said lead investigator for the study, Michael Becker, M.D., Professor Emeritus of Medicine, University of Chicago. "These encouraging safety and efficacy results support the continued development of BCX4208 added to xanthine oxidase inhibitors such as allopurinol, and the advancement of BCX4208 into Phase 3 studies."

The frequency and types of adverse events, including infections, were similar between the groups treated with BCX4208 and placebo. No opportunistic or unusual infections were reported in either the BCX4208 treated groups or placebo. A dose-dependent decrease in lymphocytes was observed, which reached a plateau between day 57 and 85 for patients still remaining in the study. The frequency of confirmed gout flares was low, ranging from 5% to 11% for BCX4208 doses combined with allopurinol, compared to 5% for placebo plus allopurinol.

BioCryst also presented results from other BCX4208 clinical and pre-clinical studies at a poster session on Monday, November 7, 2011. The two posters presented were:

- Presentation Number 1018: "BCX4208 Synergistically Lowers sUA Levels when Combined with Allopurinol in Patients with Gout: Results of a Phase 2 Dose-Ranging Trial" concluded that synergistic mean and percent reductions in sUA level were observed with BCX4208 combined with allopurinol. BCX4208 plus allopurinol 300 mg brought 75% to 100% of gout patients to target sUA level versus 40% for allopurinol 300 mg alone. This combination was generally safe and well-tolerated, with diarrhea and headache as the most commonly reported adverse events
- Presentation Number 1026: "Nonclinical Drug-Drug Interaction (DDI) Profile of BCX4208, an Oral, Once-Daily, Novel Nonmetabolized Enzyme Inhibitor for Chronic Management of Gout" concluded that the potential for hepatic or renal DDIs is low given that BCX4208 does not induce or inhibit CYP isoforms, has low potential as a P-gp substrate or inducer, and is not a substrate or inhibitor of renal organic anion and cation transporters. Furthermore, BCX4208 undergoes renal elimination and is not metabolized by liver cells

Copies of the abstracts are available online through the ACR website at www.rheumatology.org. In accordance with the conference's embargo policy, the oral presentation and posters will be uploaded to the BioCryst website after completion of the sessions. Please refer to the Company's BCX4208 publications page.

Conference Call and Webcast

Separate from the Scientific Meeting, BioCryst will host a conference call and webcast today at 7:45 p.m. Central Time to discuss the BCX4208 results presented during the meeting. 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 BioCryst's website at www.BioCryst.com. Please connect to the website at least 15 minutes prior to the start of the conference call to ensure adequate time for any software download that may be necessary. The presentation will be archived on the site and available for replay for at least 28 days.

About Gout

Gout is a chronic inflammatory arthritis caused by monosodium urate crystal deposits in joints and the kidneys resulting from elevated serum uric acid (sUA) levels in the blood, a condition known as hyperuricemia. The consequences of gout may include intense, painful flares affecting one or more joints, impaired kidney function and joint destruction. Gout continues to grow in prevalence and severity, affecting over 17 million people in major markets, including 8.3 million in the U.S. A majority of gout patients are also treated to manage other chronic conditions, including hypertension, diabetes and/or high cholesterol. Decreasing sUA to the recommended level (less than 6 mg/dL) can reduce the risk of gout attacks over the long-term. A minority of patients treated with the current standard of care, allopurinol, achieve this therapeutic goal. There is a need for new therapies that effectively and safely get a larger portion of gout suffers to goal without the risk of drug-drug interactions. More information regarding gout and hyperuricemia is available on the CDC website at www.cdc.gov/arthritis/basics/gout.htm.

About BCX4208

BCX4208 is a novel enzyme inhibitor with the potential for once-a-day oral dosing suitable for chronic administration to treat gout. It acts upstream of xanthine oxidase in the purine metabolism pathway to reduce sUA in patients with gout and has a mechanism of action that complements xanthine oxidase inhibitors, such as allopurinol and febuxostat, in reducing uric acid production. With its unique mechanism of action, clinical activity and safety in clinical studies to date, BCX4208 is nearing the end of Phase 2 development as an add-on therapy to xanthine oxidase inhibitors to address unmet medical needs in patients with gout. To date, BCX4208 has been studied in over 500 subjects in clinical trials.

About BioCryst

BioCryst Pharmaceuticals designs, optimizes and develops novel small-molecule pharmaceuticals that block key enzymes involved in infectious diseases, inflammatory diseases and cancer. BioCryst currently has three novel late-stage compounds: peramivir, a neuraminidase inhibitor for the treatment of influenza, BCX4208, a purine nucleoside phosphorylase (PNP) inhibitor for the treatment of gout, and forodesine, an orally-available PNP inhibitor for hematological malignancies. Utilizing crystallography and structure-based drug design, BioCryst continues to discover additional compounds and to progress others through pre-clinical and early development to address the unmet medical needs of patients and physicians. 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 our 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 there can be no assurance that BCX4208 or our other compounds will prove effective in future clinical studies; that development and commercialization of BCX4208 or our other compounds may not be successful; that we or our licensees may not be able to enroll the required number of subjects in planned clinical trials and that such clinical trials may not be successfully completed; that BioCryst or its licensees may not commence as expected additional human clinical trials with BCX4208 or our other product candidates; that BCX4208 or our other product candidates may not receive required regulatory clearances from the FDA; that ongoing and future development may not have positive results; that we or our licensees may not be able to continue future development of our current and future development programs; that our development programs may never result in a commercial product or license or royalty payments being received by BioCryst; that BioCryst may not reach favorable agreements with potential pharmaceutical and biotechnology partners for further development of BCX4208 or our other product candidates; that our actual cash burn rate may not be consistent with our expectations; that BioCryst may not have sufficient cash to continue funding the development, manufacturing, marketing or distribution of BCX4208 or our other products and that additional funding, if necessary, may not be available at all or on terms acceptable to BioCryst. 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 our projections and forward-looking statements.

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BioCryst Pharmaceuticals
Robert Bennett, 919-859-7910 (Investors)
or
WCG
Catherine Kyroulis, 212-301-7174 (Media)

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