BioCryst Initiates a Phase 2b Study of BCX4208 as Add-on Therapy in Gout Patients Not Responding to Allopurinol Alone

RESEARCH TRIANGLE PARK, N.C.--(BUSINESS WIRE)-- BioCryst Pharmaceuticals, Inc. (NASDAQ: BCRX) today announced the initiation of a Phase 2b study of BCX4208 as add-on therapy in gout patients who have not responded to allopurinol therapy alone.

This randomized, double-blind, dose-response 250-patient study is designed to evaluate the safety and efficacy of BCX4208 in combination with allopurinol in gout patients who have failed to reach the serum uric acid (sUA) objective of <6 mg/dL following treatment with allopurinol 300 mg alone. The primary endpoint of the study is the proportion of subjects with sUA <6 mg/dL at day 85. The study utilizes a parallel-group design, evaluating BCX4208 at doses of 5 mg, 10 mg, 20 mg, 40 mg and placebo administered once-daily for 12 weeks, in combination with allopurinol's standard dose of 300 mg. BCX4208 doses of 20 mg per day up to 240 mg per day have been found to be generally safe and well-tolerated in more than 180 patients in short-term studies. Further details regarding this study design will be available on clinicaltrials.gov.

"We are very pleased with the clinical results generated to date, and excited to now study the efficacy and safety of 12 weeks of BCX4208 added to allopurinol in patients suffering with gout. Based on our most recent trial, we anticipate seeing clinically important reductions in serum uric acid concentrations when low doses of BCX4208 are added to the allopurinol treatment regimen," said Dr. William P. Sheridan, Chief Medical Officer at BioCryst. "We anticipate completing this study and reporting top-line data towards the end of 2011."

About BCX4208

BCX4208 is a next generation purine nucleoside phosphorylase (PNP) inhibitor with the potential for once-a-day dosing suitable for chronic administration. With its unique mechanism of action, clinical activity and safety in clinical studies to date as well as its potential synergy with approved therapies, BCX4208 has the potential to address unmet medical needs across a broad spectrum of inflammatory and autoimmune diseases. In September 2010, BioCryst reported positive results from its Phase 2 study of BCX4208 alone and in combination with allopurinol in patients with gout, announcing that the study met its primary endpoint related to serum uric acid (sUA) reduction, demonstrated a dose-response for both BCX4208 and allopurinol, and that the combination of BCX4208 and allopurinol was shown to be superior to either drug alone in sUA reduction. For more information about BCX4208 please visit BioCryst's Web site at http://www.biocryst.com/bcx_4208.

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 in development: 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 Web site 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 ongoing and future pre-clinical and clinical development of BCX4208 may not have positive results; that we or our licensees may not be able to enroll the required number of subjects in planned clinical trials of our product candidates 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 our product candidates; that our product candidates may not receive required regulatory clearances from the FDA; that ongoing and future pre-clinical and clinical 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 future product, license or royalty payments being

received by BioCryst; that BioCryst may not be able to retain its current pharmaceutical and biotechnology partners for further development of its product candidates or it may not reach favorable agreements with potential pharmaceutical and biotechnology partners for further development of its 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 its 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.

BCRXW

BioCryst Pharmaceuticals, Inc.
Robert Bennett, +1-919-859-7910 (investors)
or
WCG
Catherine Collier Kyroulis, +1-212-301-7174 (media)

Source: BioCryst Pharmaceuticals, Inc.