



## **ROCHE AND BIOCRYST ADVANCE BCX-4208/R3421 INTO PHASE II PSORIASIS TRIAL**

Birmingham, Alabama – July 16, 2007 –BioCryst Pharmaceuticals, Inc. (Nasdaq: BCRX) today announced the initiation of the first Phase II study to evaluate BCX-4208/R3421. This clinical trial, led by Roche, is designed to evaluate BCX-4208 in patients with moderate to severe plaque psoriasis.

BCX-4208 is an orally available small molecule inhibitor of purine nucleoside phosphorylase (PNP), an enzyme that is essential for the proliferation of activated T cells. With its novel mechanism of action BCX-4208 has the potential to address unmet medical needs across a broad spectrum of autoimmune diseases as well as in the area of acute transplant rejection.

Through the initiation of this Phase II clinical trial, Roche and BioCryst continue to demonstrate their strong commitment to develop BCX-4208 as a novel agent to improve therapeutic options for patients with debilitating autoimmune conditions.

"We are excited that BCX-4208 is advancing into Phase II testing," said Jon P. Stonehouse, CEO of BioCryst. "The potential for a new oral therapy that is convenient, safe and effective would be an important addition to currently available treatment options for the many millions of patients who suffer from serious autoimmune conditions around the world. BCX-4208 is the lead compound in our second generation PNP inhibitor program and the initiation of this trial represents a significant step towards demonstrating proof-of-concept with this promising approach in important disease areas."

### **About the Phase II Trial**

Phase I single ascending dose and multiple ascending dose trials in healthy volunteers were successfully completed in 2006. The Phase II study announced today is a double-blind, placebo-controlled randomized trial, comprised of three arms, each enrolling 20 patients for a total of 60 patients with moderate to severe psoriasis. Two arms will receive active drug in different dosage strengths, while patients in the third arm will receive placebo. Patients in all three arms will be dosed once daily for six weeks. The study will be conducted at multiple centers across the U.S.

### **About BCX-4208**

BCX-4208, a second generation transition-state analog inhibitor of the enzyme purine nucleoside phosphorylase (PNP), may have the potential to offer greater efficacy and activity in the treatment of autoimmune disease and transplant rejection than currently available therapies.

In 2005, BioCryst announced a partnership with Roche for the development and commercialization of BCX-4208 for transplantation and autoimmune diseases. Roche holds exclusive worldwide rights to BCX-4208 and BioCryst retains co-promotion rights in the U.S. for several indications.

### **About Psoriasis**

Psoriasis, a chronic and often painful and debilitating autoimmune disease, affects an estimated 2-3 percent of the world's population, accounting for nearly 125 million persons worldwide. The National Institutes of Health estimates that 5.8-7.5 million Americans have psoriasis and between 10-30 percent of people with psoriasis will later develop psoriatic arthritis.

Psoriasis occurs when faulty signals in the immune system mistakenly activate T-cells causing inflammation and resulting in the faster-than-normal regeneration of skin cells. Usually skin cell regeneration takes about a month, in the presence of psoriasis the skin regenerates in a few days. This overabundance of skin cells results in patches of thick, red skin which can cause significant physical discomfort. These patches of skin, called plaques, occur most often on the elbows, knees, scalp, face, palms and soles of the feet but they can appear anywhere on the body including the fingernails, toenails and the soft tissues of the genitals and inside the mouth.

### **About Autoimmune Diseases**

Autoimmune diseases occur when the immune system attacks the body's own cells rather than invading microorganisms. There are more than 80 clinically distinct autoimmune diseases (i.e. multiple sclerosis, rheumatoid arthritis and some types of diabetes), each affecting the body in different ways. Presentation of these diseases can also vary from patient to patient with the same condition, and can lead to organ failure requiring transplantation. Corticosteroids are still the mainstay of treatment

for many autoimmune diseases and physicians have to constantly balance the requirement for best possible disease control with the drug related morbidities associated with long term steroid exposure.

## **About Transplant Rejection**

The greatest threat to transplant patients is rejection of the transplanted organ by the body's own immune system. For this reason, transplant recipients must take drugs to suppress the immune response and prevent rejection usually for the rest of their lives. A regimen combining several drugs is usually given and this treatment has to be continued indefinitely. Rejection of the new kidney by the patient's immune system can lead to loss of the transplanted organ and a return to dialysis for kidney transplant recipients. For heart, lung and liver transplant patients, loss of the transplanted organ presents an immediate threat to life.

## **About BioCryst**

BioCryst Pharmaceuticals, Inc. is a leader in the use of crystallography and structure-based drug design for the development of novel therapeutics to treat cancer, cardiovascular diseases, autoimmune diseases, and viral infections. The company is advancing multiple internal programs toward potential commercialization including Fodosine™ in oncology, BCX-208 in transplantation and autoimmune diseases and peramivir in seasonal and life-threatening influenza. BioCryst has a worldwide partnership with Roche for the development and commercialization of BCX-4208, and is collaborating with Mundipharma for the development and commercialization of Fodosine™ in markets across Europe, Asia, Australia and certain neighboring countries. In January, 2007 the U.S. Department of Health and Human Services (DHHS) awarded a \$102.6 million, four-year contract to BioCryst for advanced development of peramivir to treat seasonal and life-threatening influenza. In February 2007 BioCryst established a partnership with Shionogi & Co., to develop and commercialize peramivir in Japan. For more information about BioCryst, please visit the company's web site at <http://www.biocryst.com>.

## **About Roche**

Headquartered in Basel, Switzerland, Roche is one of the world's leading research-focused healthcare groups in the fields of pharmaceuticals and diagnostics. As the world's biggest biotech company and an innovator of products and services for the early detection, prevention, diagnosis and treatment of diseases, the Group contributes on a broad range of fronts to improving people's health and quality of life. Roche is the world leader in in-vitro diagnostics and drugs for cancer and transplantation, a market leader in virology and active in other major therapeutic areas such as autoimmune diseases, inflammation, metabolism and central nervous system. In 2006 sales by the Pharmaceuticals Division totaled 33.3 billion Swiss francs, and the Diagnostics Division posted sales of 8.7 billion Swiss francs. Roche employs roughly 75,000 worldwide and has R&D agreements and strategic alliances with numerous partners, including majority ownership interests in Genentech and Chugai. Additional information about the Roche Group is available on the Internet at [www.roche.com](http://www.roche.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 the Phase II trial of BCX-4208 for psoriasis may not be successfully completed, that development and commercialization of Fodosine™ in both ALL and CTCL may not be successful, that we may not resolve satisfactorily the particulate matter issue with the intravenous formulation of Fodosine™, that DHHS could reduce or eliminate funding for peramivir, 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 clinical trials may not have positive results, that we may not be able to complete successfully the Phase IIb trial for Fodosine™ that is currently planned to be pivotal, that we may not be able to commence the proposed Phase III trial for peramivir within the time frame we currently expect or at all, that we may not be able to announce preclinical developments for additional compounds by year-end 2007 as currently proposed, 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 reach favorable agreements with potential pharmaceutical and biotech partners for further development of its product candidates, 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, current reports on Form 8-K which identify important factors that could cause the actual results to differ materially from those contained in the projections or forward-looking statements.

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