



BIOCRYST FILES IND APPLICATION FOR INJECTABLE PERAMIVIR

Birmingham, AL - Nov. 28, 2005 - BioCryst Pharmaceuticals, Inc. (Nasdaq: BCRX) has submitted an Investigational New Drug application (IND) to the U.S. Food and Drug Administration (FDA) for injectable formulations of peramivir, the company's influenza neuraminidase inhibitor. In preclinical studies, peramivir has shown potent, broad-spectrum activity against multiple strains of flu, including the H5N1 virus.

"We believe an injectable formulation of peramivir has considerable potential for treating life-threatening strains of influenza," said Dr. Charles E. Bugg, Chairman and CEO of BioCryst. "This IND filing is an important step towards the initiation of clinical studies with injectable peramivir. If the FDA approves our development plan we anticipate Phase I human clinical testing could begin early next year."

"BioCryst is proposing to develop two injectable formulations of peramivir, including an intravenous formulation for the treatment of acutely ill patients, and an intramuscular injectable formulation for treating patients in the early stages of infection," continued Dr. Bugg. "Both of these development programs are currently being pursued in close collaboration with research groups at the National Institute of Allergy and Infectious Diseases (NIAID) at the National Institutes of Health (NIH)."

About Peramivir

Peramivir is part of a class of antiviral agents that work by inhibiting viral neuraminidase, an enzyme essential for the influenza virus to replicate and infect its hosts. In preclinical tests, peramivir has been shown to be a potent and selective inhibitor of influenza A and B neuraminidases and the compound was generally well tolerated in extensive clinical studies as an oral formulation. To date, both intravenous and intramuscular formulations of peramivir have been evaluated in pre-clinical animal models with success.

There are currently four drugs available for the treatment of seasonal influenza, but there are no drugs yet approved specifically to treat avian influenza (H5N1). In pre-clinical studies, multiple avian influenza strains, including H5N1 have been shown to be sensitive to peramivir, leading researchers to believe that in the proper formulation, the drug may be effective against the virus in humans.

BioCryst believes that injectable formulations should achieve high blood levels of peramivir in humans. These heightened blood levels may be adequate to inhibit the more virulent strains of avian flu. In addition, preclinical studies have shown that peramivir is active against influenza strains that have developed resistance to Tamiflu or Relenza, especially at the blood levels the company expects to achieve in its initial Phase I studies.

About Influenza

The influenza virus is a member of the orthomyxovirus family and causes an acute viral disease of the respiratory tract. Unlike the common cold and other similar respiratory viruses, influenza can cause severe illness, resulting in life-threatening complications. Most at risk are young children, the elderly and people with seriously compromised immune systems.

Afflicting as much as 20% of the U.S. population each year, influenza is spread through contact with an infected person, usually in the discharge from a sneeze or a cough. The average incubation period is two days, but the infection can be present up to four days before symptoms become apparent. On average, patients are infectious throughout incubation, and for a period of about five days after symptoms appear. However, those patients who are severely immunocompromised can continue to shed the virus for several weeks. The virus has a short incubation time, is easily communicable and can mutate rapidly. Adding to the risk of infection is the difficulty in distinguishing the flu from other respiratory ailments. With commonplace symptoms including a nonproductive cough, rhinitis and a sore throat, patients and doctors are often unsure of the exact nature of the infection and how to treat it. Additionally, because influenza causes a weakening of the immune system, it can lead to secondary infections from viral or bacterial pathogens including certain types of pneumonia. Among high-risk patients pneumonia or the exacerbation of chronic cardiac or pulmonary conditions can often result in death.

Currently there are two ways to reduce the impact of influenza: vaccination or antiviral drug therapy. There are, however, limitations associated with both. Vaccination, while the most effective way to prevent influenza, is not always active in elderly or immunocompromised patients – those that need it most. Additionally, the ability to rapidly mutate means the virus circulating may not be the one the vaccine protects against. Conversely, currently available antiviral therapies can be highly effective but often come with unpleasant side effects including nausea and vomiting.

BioCryst is exploring opportunities related to the drug peramivir, one of a new class of antivirals, the neuraminidase inhibitors. The enzyme neuraminidase is responsible for the release of viral particles from infected cells. These viruses then spread the disease and may also assist in spreading the virus through the mucus allowing it to escape the host through air droplets. By inhibiting neuraminidase, it is believed that peramivir can stop the spread of the disease within the host and decrease viral shedding - an important advance in the management of influenza. Additionally, because the active site of influenza neuraminidase is similar among different sub-types, the company believes Peramivir may be effective in the treatment of influenza regardless of the particular strain. It is also effective in high doses against most of the known influenza drug-resistant mutants.

About BioCryst

BioCryst Pharmaceuticals, Inc. designs, optimizes and develops novel drugs that block key enzymes involved in cancer, cardiovascular diseases, autoimmune diseases, and viral infections. BioCryst integrates the necessary disciplines of biology, crystallography, medicinal chemistry and computer modeling to effectively use structure-based drug design to discover and develop small molecule pharmaceuticals.

BioCryst's lead product candidate, Fodosine™, is a transition state analog inhibitor of the target enzyme purine nucleoside phosphorylase (PNP). The drug is currently in a Phase IIa trial for patients with T-cell leukemia and a combination IV and oral Phase I pharmacokinetic trial in healthy volunteers. Results of the Phase IIa and the Phase I pharmacokinetic trial will assist in the design of a planned combination IV and oral Phase IIb pivotal clinical trial in patients with T-cell leukemia. The Company has requested a Special Protocol Assessment from the FDA for this planned trial. Additionally, Fodosine™ is currently being studied in a Phase I trial with an oral formulation in cutaneous T-cell lymphoma (CTCL) and a Phase II trial in chronic lymphocytic leukemia (CLL). BioCryst also plans to initiate a Phase I/II trial in B-cell acute lymphoblastic leukemia during 2005. Fodosine™ has been granted Orphan Drug status by the U.S. Food and Drug Administration for three indications: T-cell non-Hodgkin's lymphoma, including CTCL; CLL and related leukemias including T-cell prolymphocytic leukemia, adult T-cell leukemia, and hairy cell leukemia; and for treatment of B-cell acute lymphoblastic leukemia (ALL).

Additionally the FDA has granted "fast track" status to the development of Fodosine™ for the treatment of relapsed or refractory T-cell leukemia. A Phase Ib study with BioCryst's second-generation PNP inhibitor, BCX-4208, was recently initiated and is being conducted with the goal of initiating Phase II studies in patients with psoriasis in 2006. BioCryst has re-initiated clinical development of peramivir, an inhibitor of influenza neuraminidase, with a focus on intravenous and intramuscular delivery. Also, BioCryst has identified a clinical candidate, BCX-4678, in its hepatitis C polymerase inhibitor program, and is advancing this compound through preclinical testing with the goal of filing an IND in early 2006. For more information about BioCryst, please visit the company's web site at <http://www.biocryst.com>.

Forward-looking statements

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 we may not be able to enroll the required number of subjects in clinical trials of Fodosine™ or BCX-4208, that each of the Phase IIa trial for patients with T-cell leukemia, Phase I trial of BCX-4208, the Phase I trial of Fodosine™ for treatment of patients with cutaneous T-cell lymphoma and the Phase II trial of Fodosine™ for advanced fludarabine-refractory CLL may not be successfully completed, that BioCryst may not commence as expected additional trials with Fodosine™ and with BCX-4208 or planned human trials with peramivir or BCX-4678, that the proposed injectable formulations of peramivir may not be safe or effective in humans, that Fodosine™, BCX-4208, peramivir, BCX-4678 or any of our other product candidates may not receive required regulatory clearances from the FDA, that Phase IIa clinical trials of Fodosine™ may not show the drug is effective over the 6-week period, that ongoing and future clinical trials may not have positive results, that we may not be able to obtain a Special Protocol Assessment or otherwise be able to complete successfully the Phase IIb trial that is currently planned to be pivotal, that we may not be able to continue future development of Fodosine™, BCX-4208, peramivir, BCX-4678 or any of our other current development programs including tissue factor/factor VIIa, that Fodosine™, BCX-4208, peramivir, BCX-4678 or our other 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 and the latest Form S-3 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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