

## **BioMarck Pharmaceuticals Initiates Phase 2 Clinical Study**

***BREATH 1 study will assess effectiveness  
of BIO-11006 Inhalation Solution for COPD***

**Research Triangle Park, N.C (June 26, 2008)** -- BioMarck Pharmaceuticals, Ltd. announced today that it has initiated the Phase 2 clinical development program of BIO-11006 Inhalation Solution, a novel treatment for chronic obstructive pulmonary disease (COPD). BIO-11006 potentially represents a significant advance in the treatment of COPD due to its novel dual mechanism of action: inhibition of both mucus hypersecretion and pulmonary inflammation.

"Building on the positive safety data generated in our Phase 1 studies, BioMarck has initiated enrollment in a robust Phase 2 study that is designed to establish proof-of-concept for BIO-11006 as an effective treatment for COPD," said Ted Murphy, Vice President of Research & Development for BioMarck Pharmaceuticals. "We are optimistic about the potential for BIO-11006 to significantly advance the treatment options for COPD."

The BREATH 1 study (BIO-11006: Respiratory Effectiveness of A Targeted Therapeutic) is a randomized, double-blind, placebo-controlled, multi-center Phase 2 study in which participants will be administered 1 of 3 doses of BIO-11006 or placebo for 21 days. The study is designed to enroll 162 COPD patients with chronic bronchitis at 10 sites in the United States. Efficacy endpoints in the study include assessments of lung function (e.g., FEV<sub>1</sub>), COPD symptoms, and exercise capability. Safety will be closely monitored throughout the study by assessment of adverse events, laboratory parameters, electrocardiograms, and pulmonary function tests. The 3 dose cohorts in this study will be completed sequentially, and BioMarck expects that the first cohort will be completed by the end of 2008; complete enrollment of the planned 162 patients is expected to take 12 to 15 months. Conduct of this study is supported in part by an SBIR Award (Number R44HL073591) from the National Heart, Lung, and Blood Institute. The content of this release is solely the responsibility of BioMarck and does not necessarily represent the official views of the National Heart, Lung, And Blood Institute or the National Institutes of Health.

### **About BioMarck Pharmaceuticals**

BioMarck Pharmaceuticals, Ltd. is a privately owned biopharmaceutical company dedicated to the discovery and development of new drugs for the treatment of pulmonary diseases and disorders associated with the over-secretion of mucus and pulmonary inflammation. In developing its lead compound, BIO-11006 Inhalation Solution, BioMarck has chosen chronic

obstructive pulmonary disease (specifically chronic bronchitis) as its first target, but other diseases including asthma and cystic fibrosis are later disease targets. BioMarck licensed its technology on a worldwide exclusive basis from North Carolina State University. For more information on BioMarck, please visit its website at [www.biomarck.com](http://www.biomarck.com).

#### **About BIO-11006 Inhalation Solution**

BIO-11006 inhibits the function of the MARCKS protein (myristoylated alanine-rich C kinase substrate), which has been shown to be a vital component for secretion of mucus and inflammatory mediators. These two inhibitory aspects of BIO-11006 Inhalation Solution have been demonstrated in several different animal models of airway disease.

#### **About COPD**

It is expected that more than 50 million individuals worldwide will suffer from COPD by 2010. In the United States alone, COPD affects at least 12 million patients and causes 120,000 deaths per year, making it the 4th leading cause of death. COPD is generally defined by a limitation of airflow in the lungs. This limited airflow may result from repetitive lung injury and inappropriate injury repair in lung. The airways of the lungs are normally covered by mucus that protects the airways from dehydration, pathogens, chemicals, inflammation, reactive oxygen species, and particulate irritants. However, in response to repetitive irritant exposure from cigarette smoke, for example, excessive secretion of mucus and inflammation occurs. Excessive secretion of mucus and inflammation are a common and distinguishing feature of COPD/chronic bronchitis, and studies conducted in the last several decades demonstrate the contribution of excessive mucus to the restriction of airflow in the lungs. However, there are no drugs that specifically inhibit excessive mucus secretion in the lungs; development of BIO-11006 Inhalation Solution may fill this therapeutic gap. For more information visit: [www.biomarck.com](http://www.biomarck.com)

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