



KaloBios Initiates Phase 1/2 Trial of Humaneered™ Monoclonal Antibody KB001 for Treatment of Pseudomonas Infections in Cystic Fibrosis Patients

Palo Alto, CA (March 31, 2008): KaloBios Pharmaceuticals, Inc., a privately held biopharmaceutical company, today announced the initiation of a Phase 1/2 clinical trial of KB001, a Humaneered™, high-affinity antibody fragment that KaloBios is developing for the treatment of *P. aeruginosa* infections. The trial is being conducted in conjunction with the Cystic Fibrosis Foundation and its affiliated organizations.

The blinded, placebo-controlled trial, which is being conducted at over 10 sites across the United States, will enroll up to 48 patients with cystic fibrosis who will receive either one of two dose levels of KB001 or placebo. Endpoints for the trial include safety, reduction of *P. aeruginosa* bacteria, and inflammatory markers.

“KB001 is a very novel approach that targets the principal mechanism by which *P. aeruginosa* becomes pathogenic,” said Geoffrey Yarranton, Chief Scientific Officer. “We have demonstrated in both laboratory and rodent studies that KB001 is active against drug resistant strains of this bacterium.”

“We are also very pleased that the data from our Phase 1 healthy volunteer trial demonstrated that KB001 was well tolerated with no dose limiting toxicities, something very unusual for an anti-infective,” said Tillman Pearce, KaloBios’ Chief Medical Officer. “Furthermore there was no evidence of immunogenicity, a potential benefit of Humaneering™.”

Background Information

P. aeruginosa is an opportunistic pathogen that rarely causes disease in healthy people, but is a significant problem for critically ill or immunocompromised individuals. These include the approximately 70,000 worldwide patients with cystic fibrosis where *P. aeruginosa* is a major causative agent in the progressive loss of lung function resulting from recurrent and chronic respiratory tract infections with the bacterium.

A Phase 1/2 clinical trial in this case means that the data from a small previously conducted human trial of healthy volunteers indicated that there were limited or no side effects, and so KB001 is now being tested in cystic fibrosis patients between 18 and 45 years of age with *P. aeruginosa* in their lungs. KB001 is a fragment of a monoclonal antibody (a biologic drug), which means in this case the drug must be given intravenously or as an injection, but its effects may last for weeks. For more information

about the trial, go to <http://www.clinicaltrials.gov> or <http://www.cff.org/research/ClinicalResearch/Find/>. For more information about cystic fibrosis, please visit www.cff.org.

About Humaneering™

KaloBios' Humaneering™ technology is a proprietary method for converting non-human antibodies into engineered human antibodies. Humaneered™ antibodies are high affinity, but nearer to human germline sequence than is possible with other available antibody engineering methods, making them exquisitely suited for repeated use in the treatment of chronic or other therapies.

About KaloBios

KaloBios Pharmaceuticals, Inc., a U.S.-based, private monoclonal company, uses its proprietary platform technology to develop first-or best-in-class human antibody therapeutics. It currently has two programs that have completed Phase 1 trials and are entering Phase 1/2 trials. KB001 is an anti-infective for *Pseudomonas aeruginosa* infections, an issue for cystic fibrosis and intensive care patients on a ventilator. KB002 is an anti-inflammatory currently being studied as a potential treatment for rheumatoid arthritis and entering a clinical trial for persistent asthma patients. The company's Humaneering™ technology offers advantages over other methods of human antibody creation in terms of immunogenicity, potency, and manufacturing yields. For more information, visit www.kalobios.com.

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