

**Title:** A Phase 2, Randomized, Double-blind, Placebo-controlled, Repeat-dose Study of KB001-A in Subjects with Cystic Fibrosis Infected with *Pseudomonas aeruginosa*

**Principal Investigator:** Brian O'Sullivan, M.D.

**Sponsor:** KaloBios Pharmaceuticals, Inc.

**Purpose of Research**

The goal of this research is to determine if multiple doses of the experimental drug, KB001-A, are safe and effective in people with CF and chronic *Pa* infection. The study will help see if KB001-A will reduce the need for antibiotics, reduce respiratory symptoms, and improve the function of the lungs.

**Inclusion Criteria**

1. Confirmed diagnosis of CF
2. At least 2 respiratory tract cultures in the previous 12 months, with *Pa* present. The most recent positive *Pa* culture must be within 12 weeks before the Screening Visit (or obtain a positive culture at screening).
3. FEV1 % predicted  $\geq 40\%$  and  $\leq 80\%$ , based on Wang's equations for males 12 to 17 years and females 12 to 15 years, and on Hankinson's equations for older participants (Hankinson 1999, Wang 1993)
4. Received inhaled ABX for:
  - At least 84 days in the 26 weeks before the Day 0 Visit (equivalent to 3 28 day cycles), and
  - At least 28 days within the 8 weeks before the Day 0 Visit

**Exclusion Criteria**

1. Treatment with antibiotics for acute illness within the 4 weeks before the Screening Visit
2. Use of systemic corticosteroids within the 4 weeks before the Screening Visit
3. Any change in regimen of CF maintenance therapies within the 4 weeks before the Screening Visit
4. History of sputum cultures positive for *B. cepacia* complex in the 2 years before the Screening Visit
5. History of organ transplantation
6. Current smoker
7. History of drug addiction or alcohol abuse in the 12 months before the Screening Visit
8. History of hepatic disease (clinical cirrhosis or portal hypertension), renal dysfunction
9. Breast-feeding or pregnancy as evidenced by a positive blood pregnancy test
10. Receiving any investigational drug in the 4 weeks before the Screening Visit