

Helix BioMedix Antimicrobial Peptides Show Promise in Reducing Lung Infection and Inflammation Resulting From Cystic Fibrosis

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Helix BioMedix (HXBM.OB), a developer of synthetic bioactive peptides, today announced that research published in the July 2005 issue of *Antimicrobial Agents and Chemotherapy* titled "Antimicrobial Peptide Therapeutics for Cystic Fibrosis" has shown that small bioactive peptides have the potential to attack two of the components responsible for the progression of lung damage in Cystic Fibrosis disease: infection and inflammation.

The research was conducted by Lijuan Zhang, Jody Parente and Scott M. Harris of Helix BioMedix, in conjunction with Professor Donald E. Woods of the Department of Microbiology and Infectious Diseases, University of Calgary Health Sciences Centre, Professor Robert E. W. Hancock of the Department of Microbiology and Immunology, University of British Columbia and Timothy J. Falla of Helix BioMedix.

"We are excited about the findings of this research," commented Timothy J. Falla, Vice President and Chief Scientific Officer of Helix BioMedix. "Our peptides have proven to be fast acting, bactericidal and active against multidrug-resistant bacteria. In addition, certain peptides seem to exhibit anti-inflammatory, immunomodulatory, and wound healing activities in addition to antimicrobial activity. This makes them excellent candidates to help halt two of the components that are responsible for the progression of lung disease in cystic fibrosis patients."

R. Stephen Beatty, President and CEO of Helix BioMedix, added, "Growing resistance to antibiotics for the treatment of infection and inflammation in the lungs of cystic fibrosis patients is a major reason for loss of pulmonary function and is a significant contributing factor to the mortality of the disease. This is just another example of the broad range of pharmaceutical applications for which our proprietary peptides have shown early-stage promise."

In this study, 150 peptides were screened for activity against cystic fibrosis (CF) pathogens such as *P. aeruginosa*, *Stenotrophomonas maltophilia*, *Achromobacter xylosoxidans* and *Staphylococcus aureus* in the presence of factors that mimic the physiological environment of the CF lung. Peptides with good anti-inflammatory as well as antimicrobial activity were then tested in animal models for in vivo efficacy. Peptides were delivered to the lung via nebulization in three daily doses following infection, resulting in an estimated lung delivery of 10 to 15 µg per dose. The control group was treated with saline. The data suggests that the lead peptides, HBCM2, HBCM3, HBCP-2 and HB71 significantly reduced the numbers of viable bacteria in the infected lungs of rats as well as demonstrating good anti-inflammatory activity in mice. The in vitro antimicrobial coverage of most peptides was superior to most conventional antibiotics. In addition to bactericidal activity towards multiple microorganisms, some peptides also possessed potent anti-gram-positive and anti-*Candida* activity, an advantage, since those pathogens can be present in the CF lung, and other antibiotics used in CF therapy, such as tobramycin, often lack useful gram-positive and fungal coverage.

According to the Cystic Fibrosis Foundation CF, a genetic disease, affects approximately 30,000 children and adults in the United States and more than 10 million Americans are unknowing, symptomless carriers of

the defective CF gene. The major morbidity and mortality in CF are caused by the progressive loss of pulmonary function that results from a cycle of inflammation and infection. The main method of combating lung infections in CF patients is antibiotic treatment. With the increasing life expectancy of such patients due to improved care, more courses of antibiotics are used for longer terms and at higher doses, with the adverse consequence of increasing antimicrobial resistance. By 18 years of age, 80% of patients become chronically infected with *Pseudomonas aeruginosa*. *P. aeruginosa* is a difficult organism to treat in most human infections due to its high intrinsic antibiotic resistance. In addition, during the past decade, no new antibiotics have been approved for the treatment of pathogens in the CF patient lung. The observation of lack of potential resistance and/or cross-resistance makes antimicrobial peptides extremely interesting candidates for use in CF therapy.

About Helix BioMedix

Helix BioMedix, Inc. is an early-stage biotechnology company that has a portfolio of issued patents that covers six distinct classes of peptides, covering over 1 million unique peptide sequences. The company's mission is to become the industry leader in developing and commercializing small proteins known as bioactive peptides. The antimicrobial and wound healing properties of these peptides qualify them for inclusion in a wide range of both pharmaceutical and consumer products. The company is currently pursuing the development of selected peptides as topical anti-infectives and in wound healing. Non-pharmaceutical applications being pursued by Helix BioMedix include adjuvants for cosmetics/cosmeceuticals, personal care, plant health, animal health and wide-spectrum biocides. More information about the company and its proprietary peptides can be found on the company's website at www.helixbiomedix.com.