Successful Phase 2a Human Clinical Trials Just Completed

The U.S. Army seeks patent licensees for an antimicrobial decapeptide system that augments our natural immune responses to prevent and disrupt biofilm formation. This invention is especially well suited for the prevention and treatment of plaque-related oral diseases. In Phase 2a clinical trials Plaktak™ gum demonstrated safety and efficacy against plaque after 2-4 weeks of treatment in people with gingivitis.

Background & Technology

KSL-W is a member of a decapeptide family with demonstrated effectiveness to prevent biofilm formation on teeth, inhibit the growth of oral microorganisms, and reduce the development of plaque. KSL-W mimics the body’s own defense system – namely it exhibits selective toxicity for prokaryotes. The result is efficacy against supragingival plaque bacteria, but little effect on normal oral flora and low potential for drug resistance. KSL-W is readily adsorbed to tooth-like materials and effectively desorbed over time; this peptide also has good stability in saliva. The U.S. Army has formulated this peptide into an antiplaque chewing gum (Plaktak™) for sustained and improved delivery in the mouth. KSL-W readily degrades in gastro-intestinal environments causing no harm to the intestinal flora. Double-blind, randomized, controlled, dose escalation clinical trials of Plaktak™ demonstrated:
- Phase 1 single dose safety and tolerability, and
- Phase 2a multiple doses safety, tolerability, and proof of concept efficacy against plaque after 2-4 weeks of active treatment in a gingivitis population.

No serious adverse events occurred in both single and multiple doses trials.

Benefits

- **Augments natural defense:** KSL-W acts in a manner similar to the body’s defenses and augments those systems in a manner that targets threats while maintaining beneficial oral flora.
- **Broad Spectrum Effectiveness:** Efficacious against the following:
  - Plaque-causing bacteria: *Actinomyces, Fusobacterium*
  - Cariogenic bacteria: *Streptococcus mutans, S. sobrinus, and Lactobacillus acidophilus*
  - Fungi: *Candida albicans*
  - Virus: Herpes simplex virus (preliminary data)

Plaktak™ may also have anti-inflammatory capabilities by sequestering endotoxins associated with Gram-negative periodontal pathogens.

Status and Opportunity

- U.S. patents 8,778,889 and 7,494,980 – compositions and uses beyond chewing gum
- Numerous peer-reviewed articles

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