

Lead Inventors:

Ronald Crystal, M.D.

Chairman of Genetic Medicine, Weill Cornell Medical College Professor of Genetic Medicine, Weill Cornell Medical College The Bruce Webster Professor of Internal Medicine, Weill Cornell Medical College

Stephen Kaminsky, Ph.D.

Professor of Research in Genetic Medicine, Genetic Medicine, Weill Cornell Medical College



Business Development Contact:

Brian Kelly Director, Technology Licensing

(646) 962-7041 bjk44@cornell.edu

Background & Unmet Need

- Current strategies to help smokers quit include counseling and medication therapies
- However, due to the strong addictive qualities of nicotine, smokers have a relapse rate of 70% to 80% within 6 months
- One therapeutic approach is to develop an antinicotine vaccine, in which nicotine is administered to induce antibodies which can later sequester nicotine
- Because nicotine is a small molecule not seen by the immune system, nicotine (or a nicotine analog) must be coupled to a larger molecule to induce an anti-nicotine immune response
- Clinical trials of anti-nicotine vaccines show varied immune responses among participants, and only a small percentage successfully quit smoking
- Unmet Need: A nicotine vaccine which effectively induces immune response and aids in smoking cessation

Technology Overview

- **The Technology:** A conjugate of an isolated adenovirus hexon protein coupled to nicotine or a nicotine analog as a smoking cessation strategy
- **The Discovery:** Coupling the highly immunogenic adenovirus (Ad) hexon protein to the nicotine hapten AM1 increases the immunogenicity of a nicotine vaccine
- **PoC Data:** Mice vaccinated with the conjugate, HexonAM1, generated high titers of anti-nicotine antibodies
- When the mice were challenged with nicotine, IgGbound serum nicotine increased 5.2-fold compared to naïve control mice and nicotine levels in the brain were reduced by 53%
- The HexonAM1 vaccinated mice also showed significant alleviation of nicotine-suppressed locomotor behavior

Inventors:

Ronald G. Crystal Jonathan Rosenberg Bishnu De Martin Hicks Stephen M. Kaminsky

Patents: US Patent <u>10,004,811</u>

Publications: Rosenberg et al. Hum Gene Ther. 2013.

Biz Dev Contact: Brian Kelly (646) 962 7041 bjk44@cornell.edu

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- Anti-nicotine vaccine for the treatment and prevention of nicotine addiction
- Anti-nicotine vaccine for comorbid indications, including Critical Limb Ischemia or Buerger's Disease

Technology Advantages

- Demonstrated high titers of anti-nicotine antibodies that effectively suppressed the effects of nicotine
- Provides a new platform for vaccines against small molecules



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