


Viral Vecteded Vaccines and Potential for Use as Immunocontraception


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Immunocontraceptive Program

*Using Vaccines to Modify Sexual Behavior
or Interfere with Fertility*



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Vaxin-Auburn Program

- Broad technology platform
 - Application of viral/bacterial vectors
 - Oral, injected or inhaled
 - For prevention of infectious disease
 - To alter physiological function
- Unique, simple approach
- Program focus
 - Injectable immunocontraceptive for domestic animals
 - Oral immunocontraceptive for feral or wild animals

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Goals

- Single dose vaccine – by injection for companion animals and other routes for feral and wild animals
- No significant adverse effects
- Inhibition of estrus and pregnancy
- Prolonged duration of immunity
- Cost effective

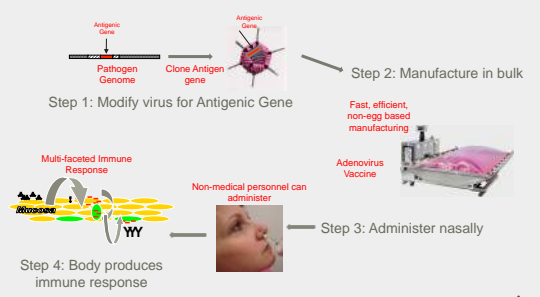
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Adenovirus Vectors

- Human adenovirus strain 5
- CMV promoter, genetic insert for encoding desired protein
- Preclinical data – viral distribution, toxicity, safety, immunogenicity & protection for flu and anthrax vaccines
- Clinical data – Seasonal and pandemic influenza in man and avian influenza in chickens

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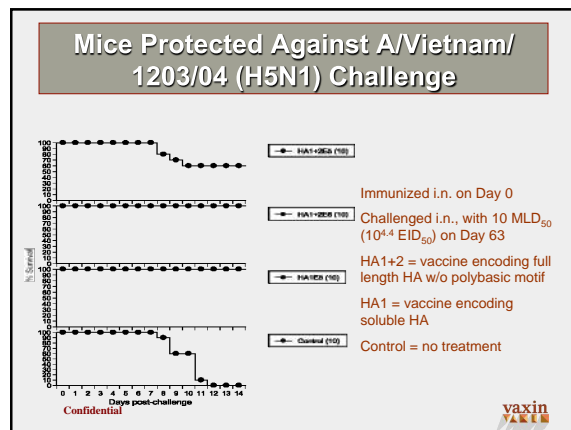
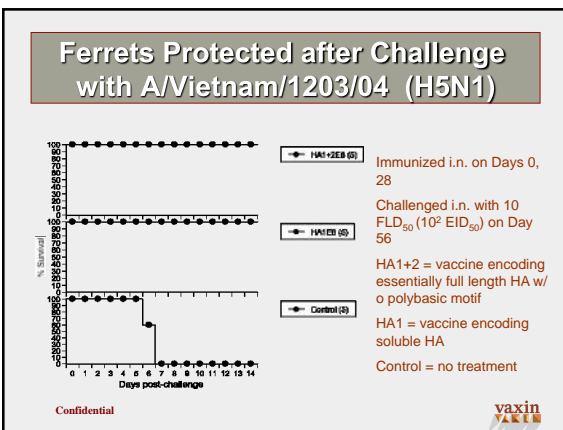
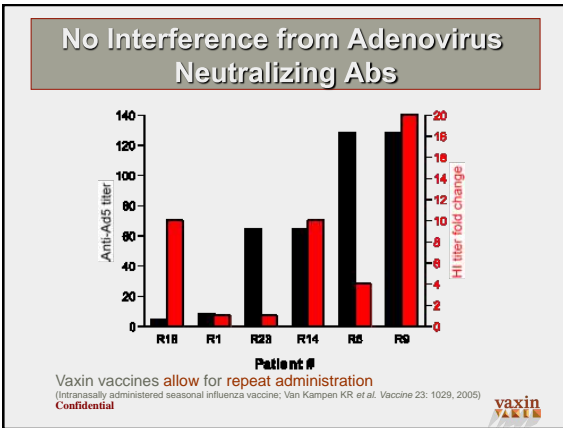
Vaxin Technology



The diagram illustrates the Vaxin Technology process in four steps:

- Step 1: Modify virus for Antigenic Gene** - An Antigenic Gene is inserted into a Pathogen Genome to create a Clone Antigen gene.
- Step 2: Manufacture in bulk** - The process is fast, efficient, and non-egg based.
- Step 3: Administer nasally** - Non-medical personnel can administer the Adenovirus Vaccine.
- Step 4: Body produces immune response** - The body produces a Multi-faceted Immune Response.

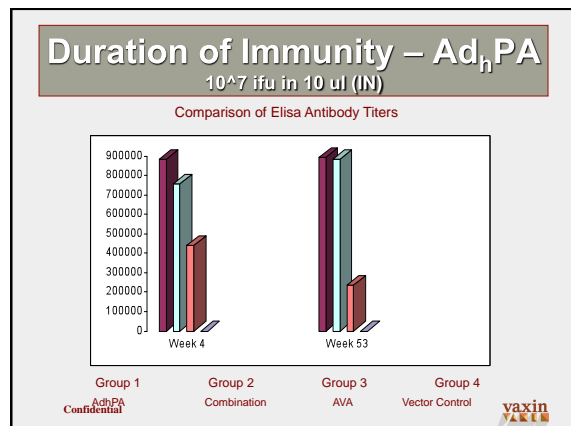
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Other Vectored Vaccines


Anthrax
 Avian Influenza
 Alzheimer's Disease

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Potential Benefits of Immunocontraception


- Reduced burden on Animal Shelters
- Prevent or interfere with transmission of infectious diseases
- Protect the environment
- Prevent loss of life and property
 - Airplanes
 - Automobiles
 - Passengers
- Minimal impact on non-intended species

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Raboral® V-RG The Vaccine Container




- Vaccine is enclosed in plastic sachet (like a ketchup packet)
- Tough, but penetrated by biting action
- Vaccine released into mouth
- Any residual vaccine becomes inactive in a short period of time following exposure to the surrounding environment

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Vaxin-Auburn Program Objective

Modification of Sexual Behavior
and/or Fertility

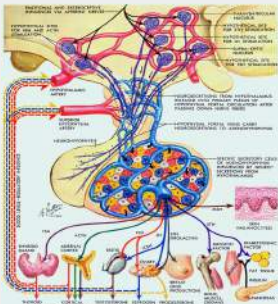
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GnRH

- Small molecule – produced in the brain
- Not a good antigen
- Takes tricks to immunize
- Stops fertility and behavior
- Before puberty permanent
- Improvac® CSL of Melbourne, Pfizer An Health
 - Available for boar taint in Australia
 - Approved by USDA for dog prostatic enlargement

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The Pathway



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Proof of Principle in Male Cats Vaccinated with GnRH



Desired Results – Immunological Neutering – Testes from normal male cat (right) and from GnRH treated male cat (left)

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Proof of Principle in Female Cats Vaccinated with GnRH

Desired Results – Immunological Neutering – Reproductive tract from normal female cat (left) and from a GnRH treated female cat (right)

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Broad Potential for Recombinant Vected Approach

Combinations of vector, insert and route of delivery allow for species specific tailored solutions

- Vectors
 - Replication competent (rc)
 - Replication defective (rd)
- Genetic inserts
 - GnRH multimers
 - Others
- Delivery
 - Oral – bacteria or viral vectors
 - Intranasal – viral vector
 - Topical – bacterial or viral vectors
 - Injected – viral vector

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Results in Targeted Animals Cats

Response to Adenovirus Vector

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Anti-tetC Antibodies in rdAd Vaccinated Cats via IM route

IM = intramuscular
Two vaccinated cats (4004, 6A2D) and two non-vaccinated cats (OF3B, 1317)

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Anti-tetC Antibodies in rdAd Vaccinated Cats via IN route

IN = intranasal
Three vaccinated cats (1B2D, 29, 2C4F) and one non-vaccinated cat (520D)

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Anti-tetC Antibodies in rdAd Vaccinated Cats via SQ route

SQ = subcutaneous
Three vaccinated cats (1C6F, 184D, 423F) and one non-vaccinated cat (1460)

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Vaxin – Auburn Specific Program Results

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Desirable Features of rdVectored Vaccines

- Safe – Non-replicating vectors do not shed or spread
- Effective – Limited number of doses required
- Invasive administration for pet animals
 - Intramuscular or subcutaneous
- Non-invasive administration for feral or wild animals
 - Oral, intranasal, topical
- Degradable by vaccinate
 - Enzymatically degraded by host's cells
- Easily manufactured

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Anti-GnRH Antibodies in rdAd Vaccinated Cats

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Testosterone Levels in rdAd Vaccinated Cats

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Issues

- Intellectual Property – rights belonging to multiple groups
- Multiple licensing agreements – royalty bearing licenses
- Pathway to licensure for manufacturing and distribution

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Licensing Process

- FDA controlled – not USDA
- Investigational New Animal Drug (INAD)
- Recombinant guidelines for vaccines
- Toxicity and safety data in target species
- Preclinical and clinical proof of efficacy
- Determination of duration of immunity
- Facility license to manufacture

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Conclusions

- GnRH shown to induce sterilizing immunity in cats
- Recombinant vaccine will induce antibodies against GnRH in cats
- Antibodies against GnRH alter hormone balance necessary for sexual behavior and reproduction
- Recombinant vectors offer multiple routes of administration for potential population control in feral wild animals
- Vaccines can be manufactured economically

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