5th International Symposium on Non-Surgical Contraceptive Methods of Pet Population Control

ACC&D Alliance for Contraception in CATS & DOGS

Approaches with Potential for Nearer-term Impact

GonaCon™ Immunocontraceptive Vaccine

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Brief History

- Developed as a single-shot reversible vaccine for managing wild deer populations
- Registered by US EPA
  - 2009, white-tailed deer (GonaCon)
  - 2013, wild and feral horses and burros (GonaCon-Equine)
  - Additional species (?)
    - Prairie dogs
    - 'Free-ranging/roaming dogs' (GonaCon-Canine, if registered)

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Why GonaCon™ Has Current or Near-Term Potential in Dogs

- Recent and on-going studies in captive dogs have demonstrated potentially contraceptive anti-GnRH titer levels and acceptable injection site reactions
- When administered in conjunction with a rabies vaccine, neither vaccine's effect is compromised

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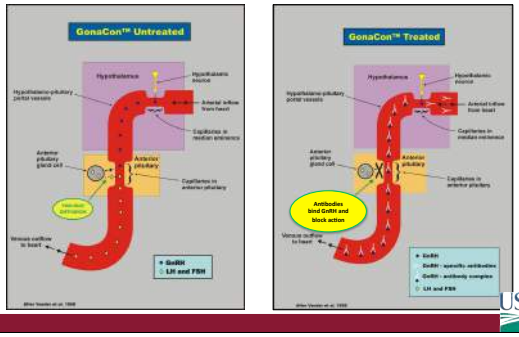
Mode of Action



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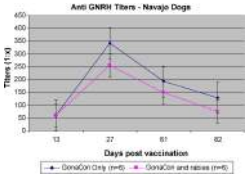
Current Status of GonaCon™

- In the United States
  - EPA registered white-tailed deer, horses and burros
  - Experimental uses on dogs and other species
- Internationally
  - Regulated as a veterinary product in many countries
  - Experimental uses on a variety of species

Summary of Key Research

Navajo Nation GonaCon Rabies Study



- **Methods:** 3 groups of free-ranging dogs:
  - 6 GonaCon only (registered)
  - 6 Rabies vaccine only
  - 6 GonaCon plus rabies vaccine
- **Results:**
  - Good rabies titers
  - Good (>1:64,000) GonaCon titers
  - No interference between rabies vaccine and GonaCon vaccine
  - Injection site reactions

Bender et al. 2009. No adverse effects of simultaneous vaccination with the immunocontraceptive GonaCon™ and a commercial rabies vaccine on rabies virus neutralizing antibody production in dogs. Vaccine 27:7210–7213.

Summary of Key Research

- Underway
  - Mexico
    - Manuscript accepted by Vaccine
    - Proposed 'dog formulation' (lower *M. avium* concentration)
    - Minor injection site reactions
      - Some initial soreness, not externally visible
    - Good anti-GnRH antibody titers 3-months post-vaccination
  - Nepal
    - Study in progress
    - Registered formulation resulted in severe injection site reactions
    - Possible study amendment to include a test group receiving the 'dog formulation' (lower *M. avium* concentration)

Summary of Key Research

- Underway
  - Oklahoma/SpayFirst
    - 'Dog formulation' – Small on-going study
- Planned
  - Tribal dog breeding study (SpayFirst)
    - EPA required Experimental Use Permit
  - South Africa dog breeding study
  - Italy dog breeding study

Target Market(s)

- U.S. 'free-ranging/roaming dog' populations
- International wild and feral dog populations
- Concurrent administration with rabies and other disease vaccination programs

Commercialization/Availability Status

- Current
  - Registered for use in wild and feral animals
    - White-tailed deer, horses, burros
  - Available through USDA APHIS Wildlife Services
- Anticipated
  - Actively seeking a licensee and manufacturer in the U.S.
  - Available for international applications

Challenges

- Confusion among potential users around feral/ domestic animal use patterns in the U.S.
- Minimizing injection site reactions without compromising efficacy
- Rigorous breeding and population study
  - Duration of effect
  - Vaccination schedule
- Manufacturing and licensing partner
  - Manufacture vaccine for APHIS registered uses
- Cost

Summary: 3 Key Takeaways

Number One:

Past studies in dogs demonstrate great potential

Number Two:

Work is still required to determine how the vaccine can be used most effectively as a fertility control agent, and/or in a rabies management program

Number Three:

APHIS is seeking a manufacturing and licensing partner