SpayVac®: a long-lasting, single-dose pZP contraceptive vaccine for deer
Presentation Outline

• A brief history of SpayVac
• A summary of SpayVac deer trials
• How SpayVac works
• Comparison with conventional contraceptive vaccines
• Who is SpayVac®-for-Wildlife, Inc.?
Grey Seals, Sable Island, Nova Scotia
A Brief History of SpayVac®

• Problem: develop a non-lethal means of controlling the Grey Seal population off Canada’s East Coast
• Key criteria: 1) long-lasting, 2) single-dose
• Dalhousie University scientists explored the use of liposomes to enhance the immune response
• The result was SpayVac®, which has proven to have long-lasting, single-dose characteristics in several species
• SpayVac®-for-Wildlife, Inc., founded in 2017, has acquired the liposome technology that underpins SpayVac’s superior performance
Grey Seals, Sable Island, Nova Scotia

Experimental Design:

- Selected animals were nursing - proven breeders, previously marked and of known age
- Treatment groups
  - 101 SpayVac®
  - 104 placebo (liposomes and adjuvant)
- SpayVac® Treatment
  - 100 µg pZP
  - liposomes
  - Freund’s Complete Adjuvant
Grey Seals, Sable Island, Nova Scotia

Fertility of Grey Seals

Year 0  Year 1  Year 2  Year 3  Year 4  Year 5  Year 10

Controls
SpayVac

Percent Pupping

SpayVac®-for-Wildlife, Inc.
Fallow Deer, James Island, British Columbia
Options Considered for Fertility Control on James Island

• Hormone implants
  • Effects on the food chain and subject animals
  • Short duration of efficacy – repeated treatments required

• Surgical sterilization
  • Too invasive and too expensive

• Immunocontraception – pZP vaccines
  • No food-chain effects
  • Minimal effects on treated animals
Animal Safety and pZP Vaccines

• Tissue-specific, non-target tissues unaffected
• Non-toxic
• Side-effects:
  • Repeated estrous cycles in contracepted females
  • Extended breeding season for males (esp. younger males)
• pZP vaccines used for >30 years
  • Generally regarded as safe and humane
The Zona Pellucida

- **Zona Pellucida (ZP)**: outer layer of mammalian ovum
- Sites on the ZP are critical to sperm binding
- ZP must be shed prior to implantation of fertilized ovum
- ZP is similar among many mammal species
## Deer Studies - Summary

<table>
<thead>
<tr>
<th>Species</th>
<th>Formulation</th>
<th>Treatment/Controls</th>
<th>% Fertile (years post-treatment)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Fallow Deer (James Island, BC)</td>
<td>100 ug pZP + FCA + VacciMax</td>
<td>SpayVac (n=41), Controls (n=111)</td>
<td>0 (n=32) 78, 0 (n=20) 78, 13 (n=8) 100</td>
</tr>
<tr>
<td>White-tailed Deer (Johnson Space Ctr, TX)</td>
<td>200 ug pZP + AdjuVac + VacciMax</td>
<td>SpayVac (n=38), Controls (ave n=11)</td>
<td>0 (n=32) 78, 0 (n=20) 78, 13 (n=8) 100</td>
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<tr>
<td>White-tailed Deer (capt) (Penn State Univ)</td>
<td>200 ug pZP + AdjuVac + Vaccimax</td>
<td>SpayVac (n=5), Controls (n=12)</td>
<td>0 (n=32) 100, 0 (n=20) 100, 13 (n=8) 100</td>
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<tr>
<td>White-tailed Deer (Penn State Univ)</td>
<td>200 ug pZP + AdjuVac + DepoVax</td>
<td>SpayVac (n=4), Controls (n=12)</td>
<td>0 (n=32) 100, 0 (n=20) 100, 13 (n=8) 100</td>
</tr>
<tr>
<td>White-tailed Deer (Fripp Island, SC)</td>
<td>200 ug pZP + AdjuVac + VacciMax</td>
<td>SpayVac (n=9), Controls (n=32)</td>
<td>0 (n=32) 62, 0 (n=20) 76, ND (n=8) 100</td>
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<tr>
<td>White-tailed Deer (Fripp Island, SC)</td>
<td>200 ug pZP + AdjuVac + DepoVax</td>
<td>SpayVac (n=11), Controls (n=32)</td>
<td>0 (n=32) 62, 0 (n=20) 76, ND (n=8) 100</td>
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SpayVac®-for-Wildlife, Inc.
Deer Results Summary - Births
Columbian Black-tailed Deer (100 ug pZP + AdjuVac + VacciMax)

<table>
<thead>
<tr>
<th>Deer #</th>
<th>Year 1</th>
<th>Year 2</th>
<th>Year 3</th>
<th>Year 4</th>
<th>Year 5</th>
<th>Year 6</th>
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</tbody>
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SpayVac®-for-Wildlife, Inc.
## Deer Results Summary
Columbian Black-tailed Deer – before / after

<table>
<thead>
<tr>
<th>Treatment</th>
<th>Doe-years</th>
<th>Fawns</th>
<th>Fertility Rate (fawns / doe-year)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Pre-treatment</td>
<td>24</td>
<td>34</td>
<td>1.4</td>
</tr>
<tr>
<td>Post-treatment</td>
<td>54</td>
<td>1</td>
<td>0.02</td>
</tr>
</tbody>
</table>

SpayVac®-for-Wildlife, Inc.
ImmunoVaccine’s Liposomes

Liposomes:
• Multi-layered vesicles
• Comprised of cholesterol and lecithin
• Prolonged antigen release
• Rapid response
• Long-lasting, single-dose
## SpayVac® – ZonaStat Comparison

<table>
<thead>
<tr>
<th>SpayVac®</th>
<th>ZonaStat®</th>
</tr>
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<tbody>
<tr>
<td>pZP antigens</td>
<td>pZP antigens</td>
</tr>
<tr>
<td>EPA Approvable adjuvant (AdjuVac or Modified Freund’s)</td>
<td>EPA Approvable adjuvant (Modified Freund’s Adjuvant)</td>
</tr>
<tr>
<td>Liposome technology</td>
<td>No special technology</td>
</tr>
<tr>
<td>Long-lasting, single-dose</td>
<td>Requires boosting</td>
</tr>
<tr>
<td>Minimal disturbance to animals</td>
<td>Repeated darting</td>
</tr>
<tr>
<td>More economical to implement</td>
<td>More expensive to implement</td>
</tr>
</tbody>
</table>

SpayVac®-for-Wildlife, Inc.
SpayVac® - VacciMax or DepoVax?

VacciMax
- Original emulsion formulation, most experience
- Provided in pre-loaded syringes
- Must be kept frozen until use
- Viscous emulsion - like mayonnaise

DepoVax
- Advanced formulation, less experience
- Provided in 2 vials to be mixed just prior to use
- Cool storage required
- Consistency of mineral oil, amenable to dart delivery

SpayVac®-for-Wildlife, Inc.
Advantages of SpayVac®

• Less disturbance and risk to the animals
• Reduced potential for late breeding and late fawns
• Improved feasibility – no need to relocate previously treated does to administer booster doses
• More economical – reduced labor costs
• Piggy-back on ImmunoVaccine’s advances for cancer and infectious disease vaccines
• Piggy-back on contract manufacturing organization (CMO) facilities
SpayVac®-for-Wildlife, Inc., mission statement: “To further research and develop contraceptive vaccines to control fertility in populations of overabundant feral and native mammals.”

SFW was founded by three experienced professionals:

- CEO—Thomas D’Orazio, MBA, with >25 years’ business experience with major pharmaceutical companies and start-ups
- VP-Research—Ursula Bechert, DVM, PhD (reproductive endocrinology)
- VP-Operations—Mark A. Fraker, CWB, RPBio, <20 years’ experience in wildlife fertility control