NovaVive
An immunobiology company

Corporate Overview

June, 2022

About the Company

- NovaVive was founded as a private company by Graeme McRae (Founder and Chairman Emeritus of Bioniche Life Sciences Inc.) in July, 2014 to introduce immunobiology-based technologies that are scientifically sound and address unmet veterinary medical needs.

- In December, 2014, NovaVive acquired the Mycobacterium Cell Wall Fraction (MCWF) technology platform that was part of Bioniche Animal Health. This potent technology is being developed by NovaVive as both non-antibiotic therapeutics and cancer therapeutics for animals.

- NovaVive also acquired the global license to MCNA for treating animal cancers. MCNA is an advanced formulation of mycobacterium cell walls and nucleic acids formulated for human applications. MCNA was advanced to Phase III in the treatment of human bladder cancer by Bioniche Life Sciences.

- NovaVive is managed by a group of experienced executives (ex-Bioniche) who collectively have successfully developed veterinary technologies that have taken large global market share in the face of rigorous competition.

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The NovaVive Product Line

The NovaVive technology has been proven to successfully treat several serious animal diseases, including cancer and bacterial/viral infections.

Amplimune® - an approved formulation of MCWF for the treatment of *E. coli* K99 infections in calves (USA, Canada, New Zealand, UAE) *(antibacterial)*

Equimune® - an approved formulation of MCWF for the treatment of viral infections in horses (USA, Australia, New Zealand) *(antiviral)*

Settle® - an approved formulation of MCWF for the treatment of endometritis in horses (USA, Australia, New Zealand, UAE) *(antibacterial)*

Immunocidin® - an approved formulation of MCWF for the treatment of mammary adenocarcinoma (aggressive mammary cancer) in dogs (USA, Canada) *(anticancer)*

Immunocidin® Equine - an approved formulation of MCWF for the treatment of sarcoids in horses (USA, Canada) *(anticancer)*

- These products are manufactured in a single-purpose, USDA/CFIA/APVMA/ACVM-approved facility in Athens, Georgia, USA

Patents:
US: 4744984, 5632995, 5759554, 6139844, 6890541
CA: 1293190, 2154689, 2170142, 2284932, 2284937, 2378888

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Antibiotic Use/Resistance

- Antimicrobial resistance happens when microorganisms change after exposure to antimicrobial drugs (such as antibiotics, antifungals, antivirals, antimalarials, and anthelmintics).
- Microorganisms that develop antimicrobial resistance are sometimes referred to as “superbugs”.
- Traditional antimicrobials are becoming ineffective and this is threatening our ability to treat common infectious diseases, resulting in prolonged illness, disability, and death.
- Antimicrobial resistance occurs naturally over time, usually through genetic changes. However, the misuse and overuse of antimicrobials is accelerating this process.
- Antibiotics are often overused and misused in people and animals, or are given without professional oversight (including being given as growth promoters in animals or used to prevent diseases in healthy animals).
- Antimicrobial resistant-microbes are found in people, animals, food, and the environment (in water, soil and air). They can spread between people and animals, including from food of animal origin, and from person to person.

Source: World Health Organization (WHO)

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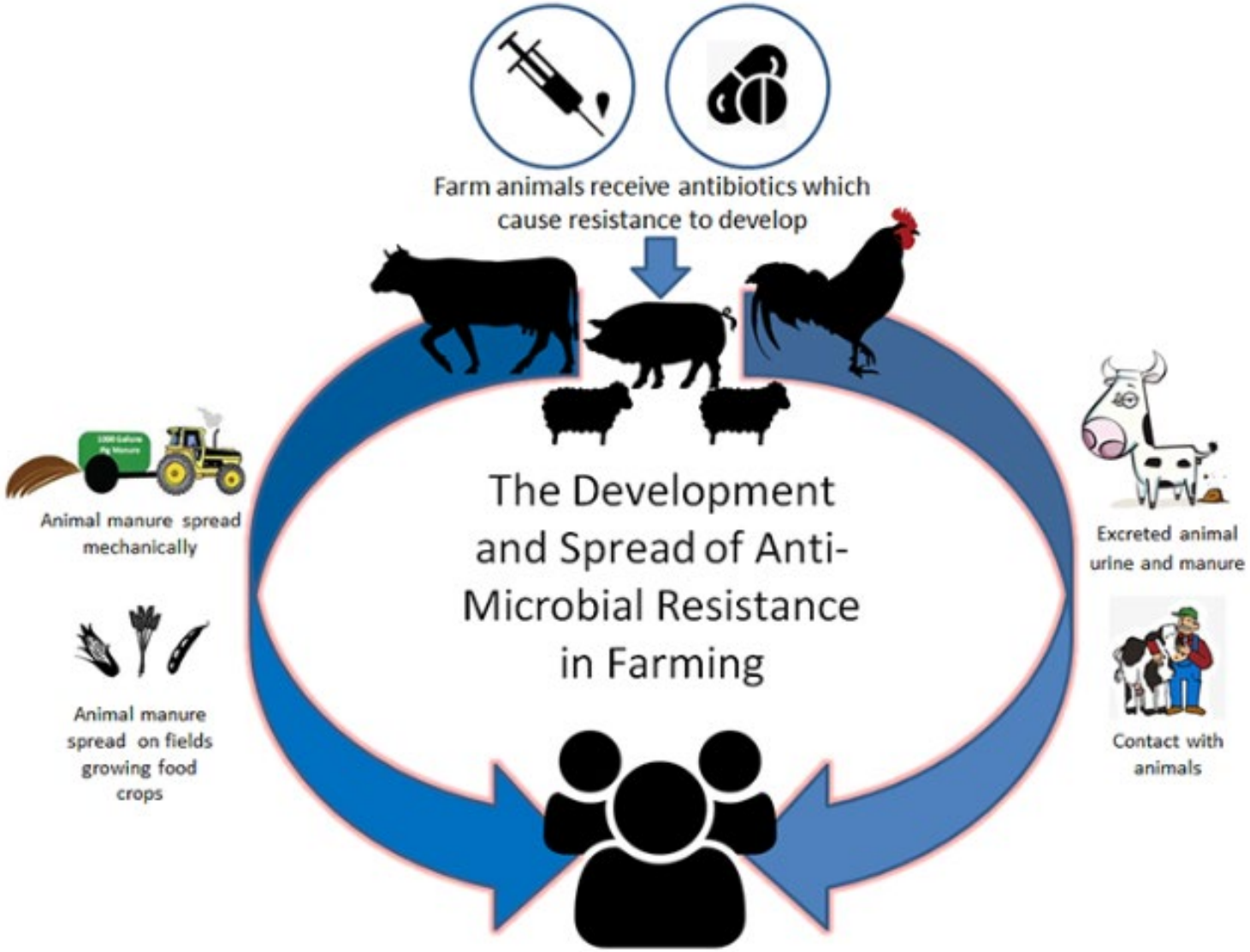

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MCWF Antibacterial/Antiviral Mode of Action

Overcoming Infections

MCWF/MCNA stimulates cells of both the innate and adaptive immune systems:

Neutrophils (PMNs)

Nonspecific Killer cells (NKs)

Macrophages & Monocytes

Dendrocytes (antigen presenting cells)

Lymphocytes (T-cells and then B-cells)

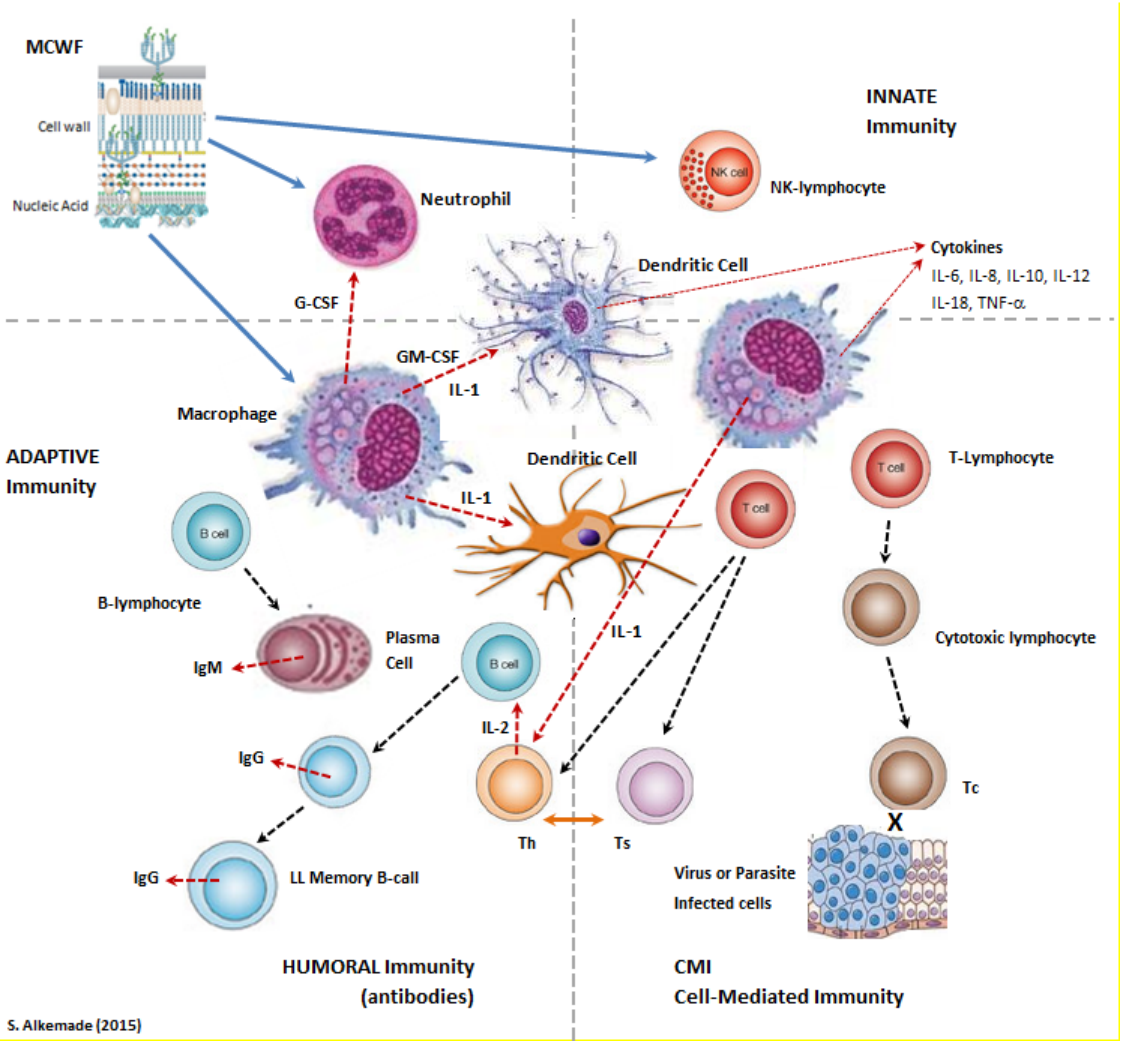
Macrophages and monocytes are stimulated to produce interleukin-1 (IL-1) which then starts an immune cascade involving many cytokines and the activation of numerous cells

Innate immune responses involve PMNs, mononuclear cells and NK-lymphocytes

Adaptive immune function is determined by the type of antigen presented and its relationship to body cells

Intracellular infections (viral) and abnormal (cancer) cells induce a cell-mediated immune (**CMI**) response

Humoral (memory) responses will help prevent future infections with the same infectious organism



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Regulatory Environment

- Every jurisdiction has its own regulatory body overseeing the regulation of animal health products, whether drugs or biologics (MCWF products are considered biologics).
- The regulatory authorities for MCWF products where they are currently approved are:
  - Canadian Food Inspection Agency (CFIA) 
  - United States Department of Agriculture (USDA) 
  - Australian Pesticides and Veterinary Medicines Authority (APVMA) 
  - Agricultural Compounds and Veterinary Medicines (ACVM) – New Zealand 
  - Ministry of Climate Change and Environment - United Arab Emirates 
- An animal health company will test its technology in an experimental indication (disease) to establish proof of concept. The company must supply a data package demonstrating safety and efficacy of a technology for the target indication/species in order to have it approved for market. The regulatory agency must pre-approve a regulatory study protocol before the study takes place.
- Timelines for animal health studies are typically shorter than human health studies.
- Rarely, a data package approved by a regulator in one jurisdiction will be acceptable for approval by a regulator in another jurisdiction, but often additional clinical studies are required.

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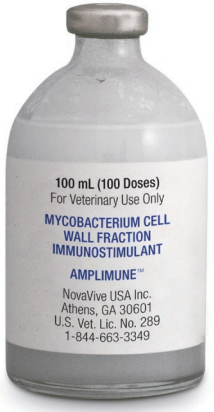
AMPLIMUNE®

for Neonatal Calf Scours

OMRI
USA · CANADA
Pour L'utilisation Biologique
For Organic Use

antibacterial

Amplimune®



- Approved for the treatment of calf scours (diarrhea) caused by *Escherichia coli* K99.
- Colibacillosis caused by *Escherichia coli* is one of the principal causes of neonatal calf diarrhea, occurring most often in the first week of life.
- A newborn calf's immune system is immature and can be overwhelmed by disease challenges in the environment; the passive immunity transferred from colostrum in their mothers' milk is not enough. Many calves do not receive sufficient colostrum.
- Studies have shown that a single dose of Amplimune® can induce an immediate innate immune response in the neonatal calf resulting in a highly effective antibacterial response.

OMRI® USA · CANADA
Pour L'utilisation Biologique
For Organic Use

Approved by regulators in USA, Canada, New Zealand, UAE

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Bovine Market Opportunity

- There are approximately 9 million dairy cattle in North America (producing ~4 million heifer calves/year).
- Approximately 5% of the dairy market is represented by organic producers
- There are approximately 28 million beef cattle in North America (producing ~19 million calves/year).
- Our competition is antibiotics (as therapeutic treatments).

Acta Veterinaria-Beograd 2017, 67 (2), 222-237
UDK: 636.2.09:[616-022.5:579.842.11
DOI: 10.1515/acve-2017-0019

Research article

MYCOBACTERIUM CELL WALL FRACTION IMMUNOSTIMULANT (AMPLIMUNE™) EFFICACY IN THE REDUCTION OF THE SEVERITY OF ETEC INDUCED DIARRHEA IN NEONATAL CALVES

ROMANOWSKI Radoslaw[1], CULBERT Rick[2], ALKEMADE Stan[2], MEDELLIN-PEÑA Maira J.[2], BUGARSKI Dejan[3], MILOVANOVIC Aleksandar[3], NESIC Sladjan[4], MASIC Aleksandar[3]*

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Reducing Pneumonia in Shipped Calves

- University of Minnesota study* involving 1,360 newborn Jersey and Jersey-cross dairy heifer calves being shipped form a nursery in Minnesota to a grower in New Mexico
- Calves were divided into one of three groups: control, pre-shipment treatment (with Amplimune®) or arrival treatment (with Amplimune®)
- The dairy operation involved in the study was very well-managed, so the overall number of disease treatment events was lower than the national average
- The calves receiving Amplimune® before transport had fewer treatments for pneumonia within the first 30 days of life
- Bovine respiratory disease complex (BRC) – which includes all diseases infecting the lower and upper respiratory tract, including pneumonia – can be caused by viral or bacterial pathogens
- BRD is one of the most common and costly diseases affecting the cattle industry, and often involves treatment with antibiotics

46% reduction in the risk of pneumonia treatments!

**data presented at the 2019 American Dairy Science Association Annual Meeting on June 26, 2019.*

A more detailed presentation was made at the American Association of Bovine Practitioners Conference in September, 2019.

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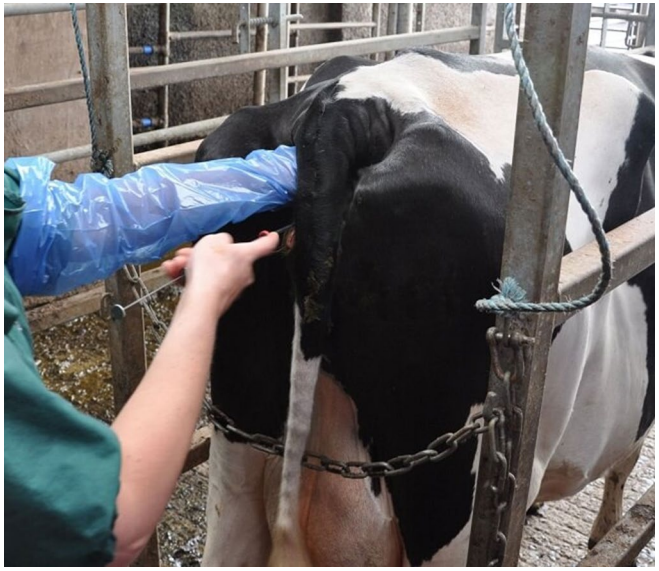
Improving Pregnancy Success in ET Recipients

- Study involved 500 embryo transfer recipient Holstein heifers
- Treatment group (n=292) received one IM dose of Amplimune (5mL) within 18 hours of heat behaviour signs (Control group (n=296) received no Amplimune)
- 45% of Amplimune-treated heifers were pregnant at Day 60 vs. 28% of Controls



- Pregnancy per embryo transfer at Day 60 was 58% (vs. 48% in Controls)
- 78% of synchronized heifers were suitable to receive an embryo at day of transfer (vs. 59% of Control heifers)
- Published in Reproduction, Fertility and Development, 2021; 33(2): 145-145

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Improving Outcomes in Organic Dairy Herd

- Study (conducted by Colorado State University researchers) involved 136 organic dairy cows
- Treatment group (n=65) received one SC dose of Amplimune (5mL) 7 days before expected calving and a second SC dose within 24 hours post-calving; Control group (n=71) received placebo (saline)
- Pregnancy was analyzed at three time points: first AI, 100 DIM and 150 DIM
- In multiparous cows (animals having more than one pregnancy), the Amplimune-treated cows outperformed the control animals at all time points:
  1. First AI: 35.6% of treated cows pregnant vs. 19.2% of controls
  2. 100DIM: 51.1% treated cows pregnant vs. 25.0% of controls
  3. 150 DIM: 64.4% treated cows pregnant vs. 40.4% of controls
- Published in Journal of Animal Science (https://academic.oup.com/jas/article-abstract/99/9/skab191/6360969

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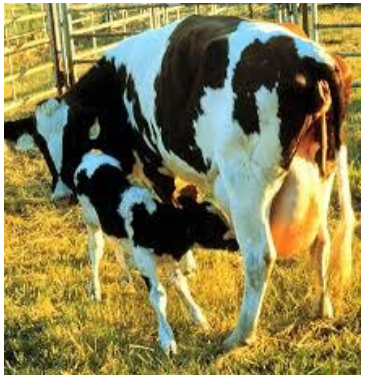
Safety in Beef Cattle

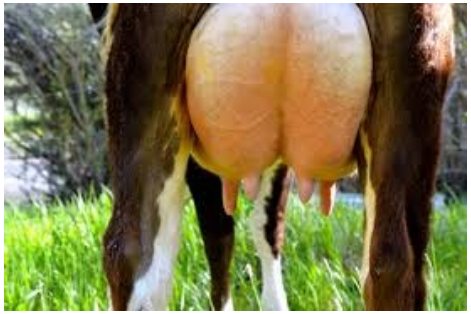
- Study (conducted by CSIRO) involved 60 weaner Angus cattle
- The cattle were assigned to one of 6 treatment groups (n=10/group) on day 0 following transportation:
  1. 2 ml Amplimune by IM injection
  2. 2 ml Amplimune by SC injection
  3. 5 ml Amplimune by IM injection
  4. 5 ml Amplimune by SC injection
  5. 5 ml saline by IM injection
  6. 5 ml saline by SC injection
- Body temperature, body weight, concentrations of circulating pro-inflammatory cytokines (TNFα, IL-1β, IL-6 and IL-12), and haematology parameters were measured at various times up to 96 hours post-treatment
- There were no adverse effects observed from Amplimune treatments
- Amplimune induced activation of the innate immune system - without causing an excessive inflammatory response.
- Researchers concluded that Amplimune can be safely administered to beef cattle at the dose rates and via the routes of administration investigated in this study
- Published in Australian Veterinary Journal https://onlinelibrary.wiley.com/doi/10.1111/avj.13156

Metritis and Mastitis in the Dairy Cow

1. Metritis (bacterial infection/inflammation of uterus)
   - Major cause of economic loss due to breeding inefficiency (affects ~20% of cows)
   - Standard therapy: antibiotics



2. Clinical Mastitis (bacterial infection of udder)
   - Major cause of economic loss due to milk discarding/culling (affects 10-20% of cows)
   - Standard therapy: antibiotics



NovaVive continues to assess the potential of Amplimune immunotherapy in these diseases as an alternative to antibiotics

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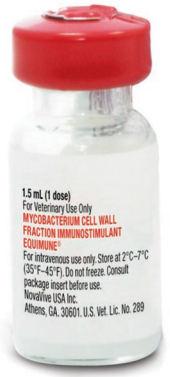
EQUIMUNE®

For Equine Respiratory Disease Complex

antiviral

Equimune®



- Approved for the treatment of Equine Respiratory Disease Complex (ERDC).
- ERDC is commonly caused by the equine strains of herpesvirus or influenza A virus; it can cause severe inflammation and damage to the upper and lower respiratory tracts.
- Controlling the viral infection early can help minimize downstream bacterial complications and secondary lung damage.
- Serious respiratory infections can ruin years of training invested in the equine athlete.
- **Equimune® is administered as a single dose by I.V. injection (treatment may be repeated every 1-3 weeks).**
- Equimune® is safe for use in all horses, including pregnant mares.

Approved by regulators in USA, Australia, New Zealand

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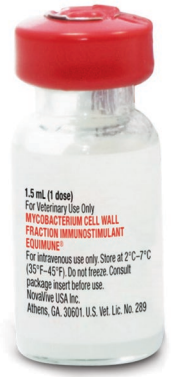
Market Opportunity



- There are ~7 million horses in the USA
- Equine respiratory disease affects approximately 10% of horses per year.
- The most common treatments are antibiotics, expectorants, cough suppressants and corticosteroids.
- This disease is not only detrimental to the horse, but also costly for horse owners (treatment cost, lost training days).
- The Company believes that there is an opportunity for Equimune® in addressing shipping fever among horses that are transported (performance horses, breeding horses and yearlings); a study will be required to confirm. Shipping fever occurs in ~10% of transported horses.
- The Company also believes that a low dose of Equimune® given to newborn foals on Days 1 and 8 could prevent many common health issues; a study will be required to confirm.

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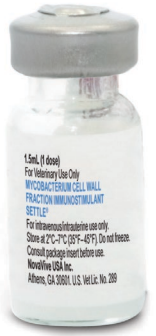
SETTLE®

for Equine Endometritis and Reproduction

antibacterial

Settle®



- Settle® is approved for the intrauterine or I.V. treatment of endometritis in the mare. Its label claim is as an aid in the treatment of endometritis caused by *Strep. zooepidemicus*, a common causative agent of endometritis in mares.
- Settle® is administered by intrauterine flush or intravenous injection.
- Settle® normalizes sub-optimal responses to infection and endometritis in problem mares.
- The product has been proven safe and effective in the treatment of post-partum endometritis, post-breeding endometritis and other infection-based endometritis.

Rogan et al 2006; Fumuso et al 2005; Fumuso et al 2007

Approved by regulators in USA, Australia, New Zealand, UAE

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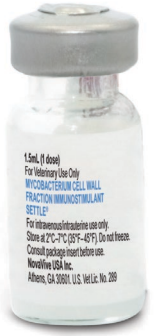
Market Opportunity



- There are ~7 million horses in the USA
- Approximately 16% of these horses are broodmares.
- At least 10% of broodmares are susceptible to endometritis ("problem mares")
- Settle has been proven to:
  - ✓ Reduce inflammation
  - ✓ Enhance bacterial clearance
  - Hasten uterine involution
  - ✓ Shorten days to ovulation (11 days)*
  - Enable normal pregnancy at foal heat**
    (65% (Settle) vs. 24% (placebo) (Fumuso *et al.* 2003)

**two doses one week apart (day after foaling and seven days later)*
***one dose (day after foaling)*

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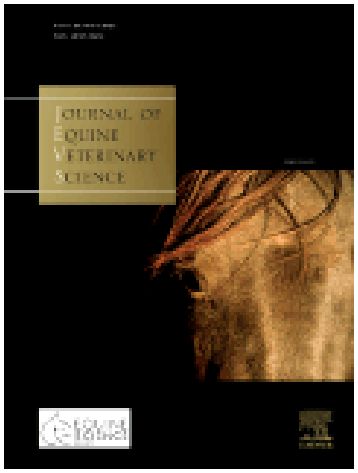
Effect of MCWF on Postpartum Involution

- Study conducted by Gluck Equine Research Center, University of Kentucky; the first study to evaluate the effect of involution on cytokine expression
- 16 postpartum mares were divided into three treatment groups:

  Group 1: Two doses of Settle, one week apart, by IV injection;
  Group 2: One IV dose of Settle every three days until ovulation was detected;
  Group 3: Two IV doses of lactated Ringers solution, one week apart.

- The mares' reproductive tracts were assessed every 72 hours and cytology and bacterial cultures were undertaken
- Inflammation was predominantly complete within 10 days postpartum
- Conclusions:
  - ✓ The use of immunomodulation may hasten this process, as it increases the expression of pro-inflammatory cytokines, decreases the time to bacterial clearance, and may also lower the amount of mucosal inflammation noted.
  - ✓ Settle should be administered in a two-dose series for maximum effect - one day and 8 days postpartum – to assist with the elimination of bacteria that may impede future fertility on the foal heat estrus cycle.



Published in the Journal of Equine Veterinary Science in April, 2020

Carleigh Fedorka, PhD, lead author

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Animal Cancers

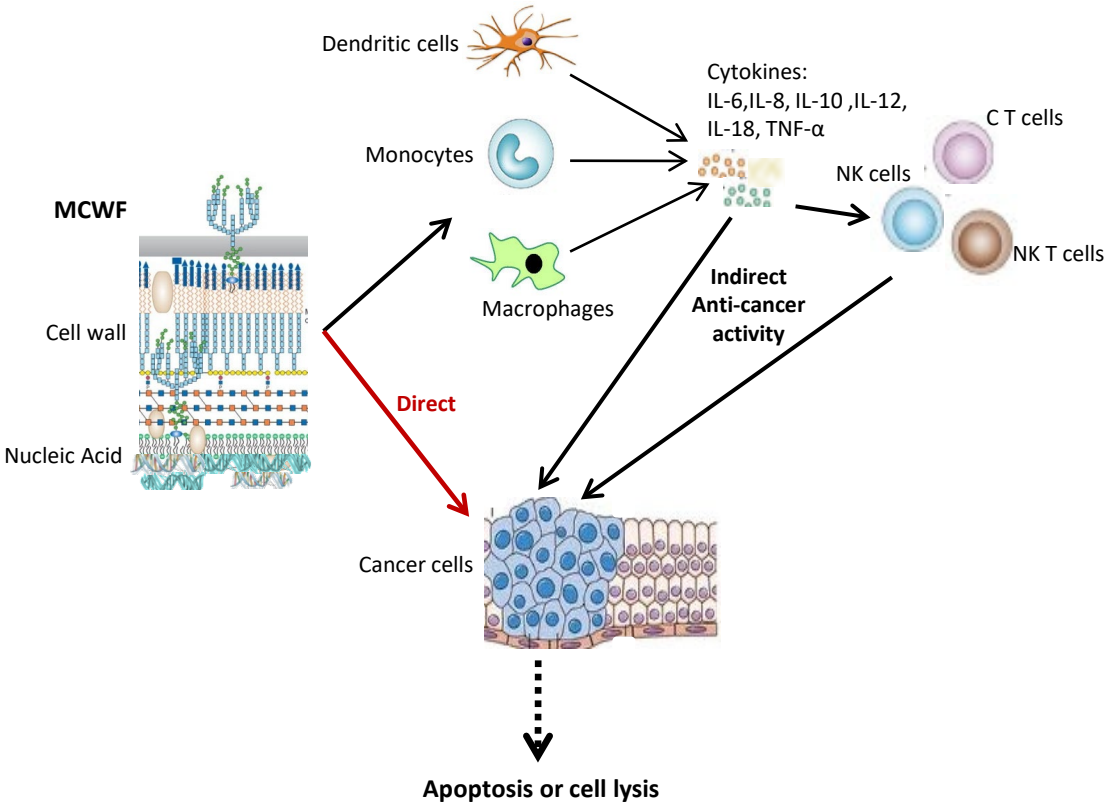
- There are more than 70 types of animal cancers.
- Cancer is the leading disease-related cause of death in dogs and cats, particularly now that more pets are living long enough (due to better health care and nutrition) to develop the disease. One in 4 dogs and cats is expected to die of cancer.
- At the same time, pet owners are seeking to treat their animals for cancer (pets are part of the family). However, there are few approved animal cancer products available to veterinarians, so they often must turn to human therapies (chemotherapies).
- Horses are also susceptible to cancer, and the number of horses with cancer is growing.
- Surgery, chemotherapy and radiation therapy are common treatments for animal cancers. There is a role for immunotherapy, and NovaVive has a registered immunotherapeutic product for the treatment of cancer in dogs and horses.

MCWF Anticancer Mode of Action

MCWF/MCNA exhibits anti-cancer activity by two mechanisms:

Indirect: immunomodulatory effect via the induction of anti-cancer cytokines and/or the stimulation of anti-cancer lymphocytes

Direct: by the induction of apoptosis (planned cell death); thereby preventing cancer cell division



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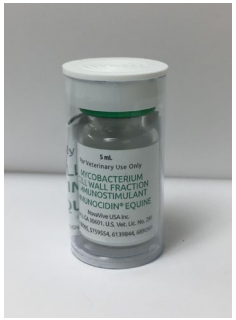
IMMUNOCIDIN® EQUINE

for

Sarcoid Treatment

anticancer



Immunocidin® Equine

- Approved for the treatment of sarcoids in horses.
- It is administered by intratumoral injection, but the response is generalized.
- Equine sarcoids are one of the most common equine skin tumors, often found around the eyes, head/face, neck, chest, shoulder, and at the site of old scars.
- Sarcoids are believed to be caused by bovine papilloma virus (BPV) transmitted by flies.
- Current treatment options include surgery, ligation, cryotherapy, topical treatment, chemotherapy, radiation therapy, or laser removal; many of these treatments incur side effects. Immunotherapy is a new, safe and effective option.
- Immunocidin® Equine has a high post-treatment, tumor-free rate, is well-tolerated, has minimal side effects and has an excellent safety profile.

Approved by regulators in USA, Canada

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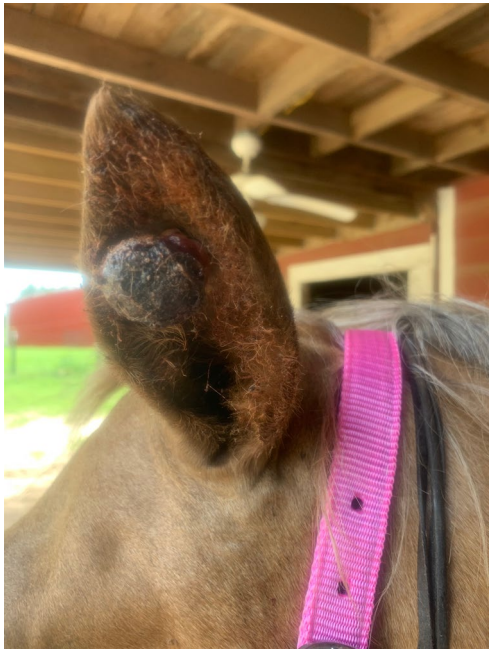
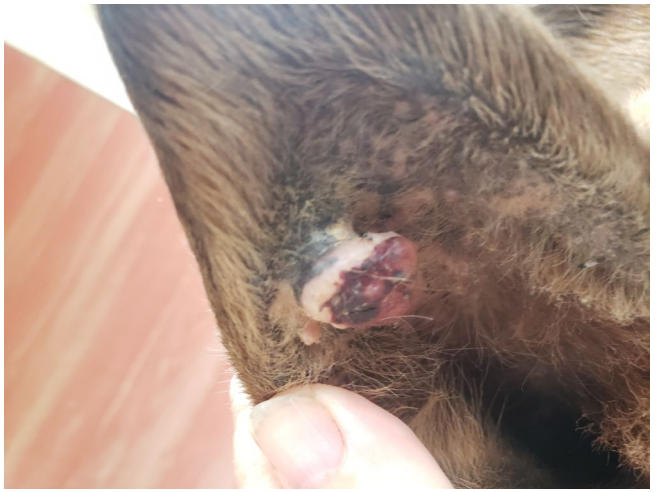
Immunocidin® Equine Efficacy



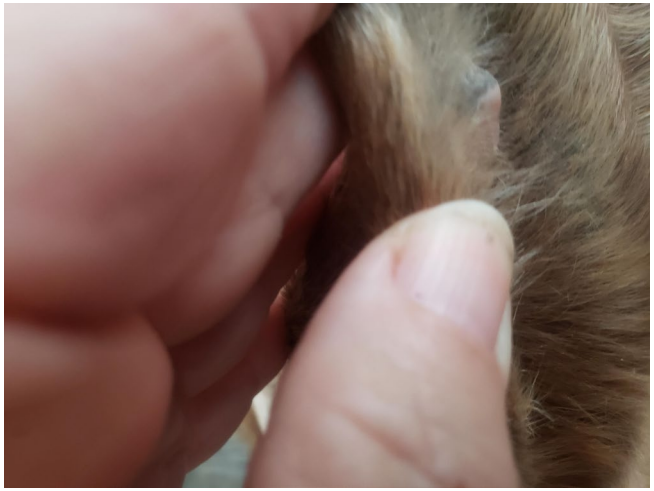
-1 large and 1 small tumor on left ear (nodular, fibroblastic)

-no previous treatment

-1 mL of product administered (IT) at base of tumors two weeks apart



-following second treatment



-final outcome

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Effect of Immunocidin Equine on Sarcoids

Stephanie S. Caston, DVM, DACVS-LA, Principal Investigator

Journal of Equine Veterinary Science

- Iowa State University (ISU) College of Veterinary Medicine conducted a study with Immunocidin® Equine to treat sarcoids; the study was focused on standardizing treatment protocols and assessing the product's efficacy and safety
- Study data are being published in the Journal of Equine Veterinary Science (pre-proof now available online)
- 17 horses with diagnosed sarcoids were enrolled; each received Immunocidin Equine by IT injection at the initial visit and then at 2-week intervals thereafter for an average of four injections per case.
- Study results:
  - ✓ Nine cases (52.9%) were completely resolved at the end of the study period or at the time of final follow-up (an average of 9 months post-final treatment).
  - ✓ Three cases (17.6%) were reported as improved, but not resolved.
  - ✓ Three cases were discontinued from the study as the tumors were not resolving after four treatments.
  - ✓ One case involved two masses, one of which was resolved with treatment, while the other had small regrowth.
  - ✓ The final case was lost to follow-up.

  All cases had mild to moderate swelling of the injection site (transient; resolved with no treatment or NSAIDs). Some cases had discharge after two or more injections.

  No serious systemic side effects or complications were encountered during the study.

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IMMUNOCIDIN®

for

Canine Mixed Mammary Tumors and Mammary Adenocarcinoma

anticancer

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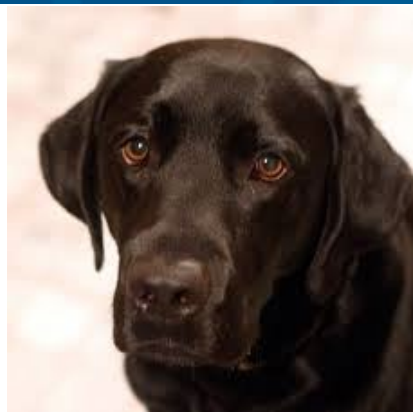
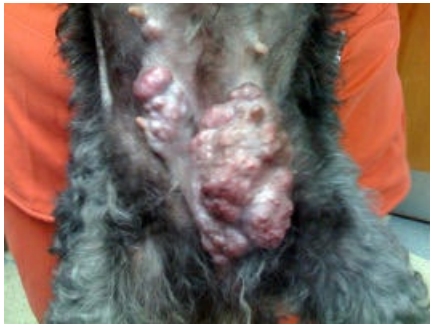
Canine Cancer Overview



- Cancer is the most common cause of death in dogs over the age of 2 years, and 1 in 4 dogs will die of cancer. In the U.S., there are approximately 70 million dogs and the incidence of cancer is approximately one in ten per year.
- The Company conservatively estimates that ~1,000,000 U.S. dogs are diagnosed with cancer each year. Of these:
  - ~300,000 dogs are euthanized after diagnosis
  - ~700,000 dogs are treated at an oncology specialty clinic, where they receive long-term palliative care, surgery, or chemotherapy (alone or in combination with other therapies)
- For those dogs receiving chemotherapy treatment, they may suffer debilitating side effects, including neutropenia (low white blood cell count).
- Chemotherapy treatment can cost a dog owner thousands of dollars per course of treatment.

NOTE: Unlike human medicine, there is no universal, central reporting mechanism for collecting data on cancer cases in veterinary medicine. Also, not all suspected cancer cases are diagnostically confirmed (many animals are euthanized prior to definitive diagnosis of tumor type).

Immunocidin®



- Approved for the treatment of mixed mammary tumor and mammary adenocarcinoma (breast cancer) in dogs.
- Administered by intratumoral injection.
- Provides increased tumor-free survival; a strong palliative response is often reported.
- Well-tolerated by dogs, including older animals and those with health complications (including chronic cardiovascular and renal disease).
- A treatment option for dogs that are poor surgical risks.
- May be used safely in-clinic with no risk to clinic personnel.
- Mammary tumors are relatively uncommon in North American dogs due to the routine spaying of female dogs.

Approved by regulators in USA, Canada

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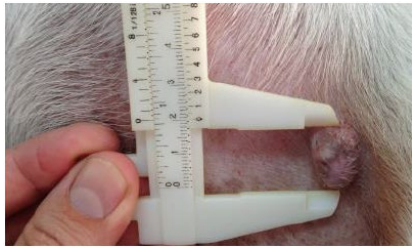
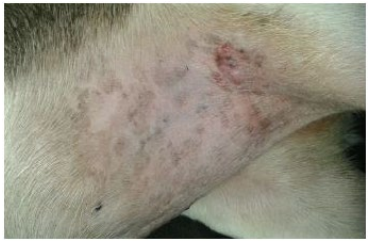
Market Opportunity

- Canine cancer represents a large unmet need that is growing exponentially with treatments highly valued.
- Studies have demonstrated clinical response in other canine cancers, including mast cell tumors, hemangiosarcoma, osteosarcoma and transitional cell carcinoma (bladder cancer).
- Clinical response has also been seen in the restoration of white blood cell count following chemotherapy treatment, thus reversing neutropenia.
- The product has been proven safe to administer by IV injection and intravesically.

Mast cell tumor (pre-treatment)



After 4th Treatment



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Further Immunocidin® Research

- Immunocidin® is being administered in combination with chemotherapy for several canine and feline cancer patients by Dr. Jeannette Kelly and the team at Veterinary Cancer Care (New Mexico).
- Enrolment has been ongoing since June, 2016 and is continuing.
- Dr. Kelly presented her first data analysis at the American College of Veterinary Internal Medicine Forum in June, 2018, in which she concluded that Immunocidin® is safe to administer by I.V. injection.

- Many of the treated animals had their survival time extended by weeks or months.
- A second presentation was made by Dr. Kelly at the Veterinary Cancer Society Annual Meeting in October, 2019.

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Summary

- NovaVive is a dynamic specialty animal health company with a revenue-generating base business and significant potential for growth via aggressive marketing, registrations in new jurisdictions and development of new formulations.
- With investment in further product development and marketing, and expansion into global markets, NovaVive believes it can grow revenues exponentially.
- The NovaVive management team has the experience to develop, manufacture, register and market its proprietary technologies; the Company markets products to veterinarians directly in the U.S., Canada, Australia and New Zealand and utilizes distribution partners in smaller markets.
- The Company has a solid marketing strategy that is being well-received by veterinarians, livestock producers and horse and dog owners.

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Thank-you!

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