NovaVive
An immunobiology company

Business Update

Fall, 2020

Volume 6, Issue 3

Message from the President

As the global COVID-19 pandemic continues, NovaVive is working hard to ensure a steady supply of immunotherapeutics for our customers. There is no doubt that the pandemic has impacted the veterinary community, as well as horse owners and cattle producers. Yet, NovaVive has been able to safely continue production and supply of our entire product line, and we're grateful to the NovaVive team for their ongoing efforts to ensure no supply disruptions.

During times like these, we are reminded of the importance of a healthy immune system to fight disease, whether bacterial, viral or cancerous in nature. Our products are all designed to boost the natural immune system to make it more able to take on pathogenic invaders.

It is important to note that all of our products are approved by regulatory authorities prior to being offered for sale in the marketplace.

The latest approval has come from New Zealand, where the Agricultural Compounds and Veterinary Medicines (ACVM) agency gave us the green light to sell Amplimune.

A new regulatory approval is not an easy nor speedy achievement. Our preliminary submission was made to ACVM more than two years ago. The process involves the regulator asking questions about the file, preparing responses, leading to further points of clarification, and so on.

One of the NovaVive team members, Dr. Stan Alkemade, was instrumental in co-ordinating the regulatory submission and follow-up materials for ACVM. Lynn Bailes, our Production Manager, was also a critical player in helping to achieve this latest corporate milestone.

I'm proud to lead a company that offers a natural therapy for animals that is effective, safe, and meets stringent standards for quality.

Amplimune® Approved for Sale in New Zealand

We are pleased to receive approval for our calf scours immunotherapy - Amplimune® - by Agricultural Compounds and Veterinary Medicines (ACVM) in New Zealand.

Amplimune reduces the clinical signs and mortality associated with *E. coli* K99 diarrhea in neonatal calves.

The product is an emulsion of mycobacterium cell wall fractions (MCWF) that enhances innate immunity to fight bacterial infections without the use of antibiotics. ACVM has approved Amplimune for intravenous administration with zero withdrawal days for slaughter.

Amplimune is a potent immunomodulator that is an emulsion of mycobacterium cell wall fractions (MCWF). When injected into the animal, it enhances both innate and adaptive immune responses to fight bacterial infections without the use of antibiotics. The product has previously received regulatory approval in the USA, Canada and the United Arab Emirates. Amplimune is OMRI listed in the USA and Canada for use in organic production.

NZ is home to ~3.6M beef cattle and ~6.5M dairy cattle

Antibiotic resistance is an ever-increasing problem in both humans and animals, according to the World Health Organization. It occurs when micro-organisms change after exposure to antibiotics, becoming "superbugs" that no longer respond to traditional treatments. This can result in prolonged illness, disability and death. Antimicrobial resistance occurs naturally over time, usually through genetic changes. However, the misuse and overuse of antibiotics (in both animals and people) is accelerating this process.

www.NovaVive.ca

agilis

Having met the rigorous efficacy and safety standards of the ACVM, we are excited to be taking this proactive step to help New Zealand cattle producers curb antibiotic use in their herds.

NovaVive has appointed Agilis Vet Ltd as its distributor for Amplimune in New Zealand. Agilis is a New Zealand veterinarian-owned company, supplying and marketing quality production animal health products to Veterinary clinics throughout New Zealand. All products marketed by Agilis have been approved by ACVM before introduction to the marketplace. Agilis understands the importance of science-based products and has confidence in supplying the New Zealand market with high quality products. Visit www.agilis.nz for further information.

Palliation Study with Immunocidin® Gets Underway

A clinical study evaluating Immunocidin® as a palliative therapy for malignant cancer is just getting underway. The study goal is to increase the comfort and well-being of the animals with Immunocidin and, therefore, maintain or improve the overall quality and duration of their remaining life. The multi-site study will involve veterinary clinics in the USA and Canada, and is financially supported by the USA-based Canine Cancer Alliance (CCRA).

The idea for this study arose from another (retrospective) study conducted by Dr. Jeannette Kelly, a veterinary oncologist from New Mexico. Dr. Kelly presented her data at the Veterinary Cancer Society Annual Conference last October. She reported that 8 dogs with Lymphoma who received Immunocidin along with chemotherapy enjoyed extended survival times ranging from 4.4 months to 40.9 months. Dr. Kelly's data suggests that Immunocidin can help

to extend the life expectancy of dogs with cancer.

Immunocidin has regulatory approval in the USA and Canada for the intratumoral treatment of canine mammary tumors (breast cancer). This new study is assessing the efficacy of Immunocidin as a solo palliative therapy for dogs that have been diagnosed with different malignant cancers (measurable tumors). Reduction of pain, progression of the tumor(s), and the overall quality of life will be evaluated. Each eligible dog will be administered the product intravenously (3 times) and orally (9 times).

Additional protocol details are available at https://ebusiness.avma.org/aahsd/study_search_results.aspx (study # AAHSD005171).

Immunocidin stimulates the dog's immune system to help fight disease. The product is an emulsion of mycobacterium cell wall fractions and -bacterial nucleic acids, which have been shown to induce apoptosis (programmed cell death) in cancer cells while not affecting normal cells. Chemotherapy tends to destroy all types of cells in the body. Immunocidin also stimulates the activation of immune cells (macrophages and T-lymphocytes) to kill cancer cells. It is contemplated that Immunocidin given as a palliative therapy could help to alleviate dis-comfort and support improved appetite, mobility and sleep in dogs with cancer, and also may help to reduce the progression of the tumor(s).

An Extended Lease on Life for Arthur, the Labradoodle

When 12-year-old Labradoodle Arthur Belanger lost his playmate, Mabel, in the fall of 2018, his owners believed he was lonely and sad. He certainly didn't have his normal bounding energy and he started having elimination accidents in the house.

Arthur paid a visit to Moira Veterinary Clinic in Belleville, Ontario, Canada where Dr. Chris Tummon diagnosed that Arthur was suffering from bladder cancer. Unfortunately, the prognosis was grim, and his life expectancy was less than two months.

An advanced formulation of Immunocidin had been taken to Phase III clinical testing in human bladder cancer by Bioniche Life Sciences Inc., so NovaVive believed it was likely that Immunocidin might help Arthur.

Dr. Tummon agreed to try Immunocidin treatment for Arthur, and weekly treatments were started. "He was put to sleep and his bladder was catheterized," said Stacey Belanger. "Then Dr. Tummon put the medicine into his bladder and turned him over after 30 minutes to ensure both sides received equal treatment. It was basically an hour treatment once a week for 2 months and then every two weeks following that."

Stacey and her family were surprised at the change in Arthur's demeanor. "The treatment immediately brought Arthur back to his fun-loving self," said Stacey. "He had more energy and was playful. We had an amazing Christmas with him."

The Belangers got a new puppy playmate for Arthur and, with his newfound energy, Arthur played with the puppy and took daily long walks with his family. They supplemented Arthur's food with eggs and sardines to try and keep him strong and healthy.

In early July, 2019, Arthur began to lose weight and was less interested in longer walks. He slept more and was beginning to look ill again. Upon the recommendation of Dr. Tummon, the Belangers decided to

let Arthur go. "Although saying goodbye was sad, we had almost 7 extra months of wonderful time with him that we would not have had," said Stacey.

"I cannot say strongly enough how thankful we are as a family that we were given this extra time with Arthur, thanks to NovaVive."