

REGRESSIN FACT SHEET

Immunotherapy is an effective means of managing various forms of disease. From allergy shots to treating specific diseases, immunotherapy has emerged as an integral part of practical medicine. At the forefront of this technology is immune stimulation. For decades, it has been known that some types of organisms possess the ability to stimulate the immune system of other animals if introduced in a controlled manner. BIONICHE Animal Health has developed and marketed an immunotherapeutic which captures the immunostimulant abilities of one such organism.

The Immune System

Circulating throughout the body are a number of cells referred to as the cells of the immune system. Billions and billions of these cells flow in the bloodstream, pushing through and around tissues and organs of the body. In their infancy, these cells go through a "training" process where they are taught to recognize other cells, tissues and chemicals which are ordinarily found within the body. As they emerge and begin travelling through the body, they contact the 'self' components on a regular basis. However, if the body has encountered some form of bacteria, virus, fungus, or simply foreign material (dust), the cell responds by destroying or inactivating the foreigner. If there is a great deal of foreign or 'non-self' material, the cell, recognizing the foreigner, rapidly divides to produce more cells which can help destroy the invader. Concurrently, the cell sends help messages to other immune system cells by chemical messengers. As other cells receive the help signals, they rush towards the source of the signal and assist in destroying the invader. In the end, the invader is overcome by the cells of the immune system.

The Nature of Tumors

Tumors and some viruses present a unique problem to the immune system. Either they are not recognized by the immune system as being foreign, or they infect the host's cells. Once inside a host cell, the immune system cannot recognize the invaders as foreign or non-self. Therefore, the invader "hides" from the immune system.

Immunotherapy - Regressin™

As mentioned, some organisms possess the ability to stimulate the immune system of another animal if the organism is introduced in a controlled manner. BIONICHE Animal Health's immunostimulant is a specific strain of mycobacteria which is a specific organism with immunostimulatory properties. The cell wall of the organism has been purified and fractionated to capitalize on its immunostimulatory abilities. If injected into an animal which is ill or possesses a tumor, the immunostimulant activates the body's immune system to react to the problem more quickly and efficiently.

Choosing Tumor Therapies

Small tumors which are not bothersome to the animal may be left untreated at the discretion and advice of the consulting veterinarian.

Traditionally, tumors have been treated by surgical procedures. The animal is anaesthetized, and the tumor mass removed. This procedure provides cosmetically appealing results. However, the nature of tumor cells is that they are extremely well adapted for growth under extreme conditions. Should any of the tumor remain in the animal following surgery, the tumor will most likely become re-established.

Immunotherapy involves activating the animal's immune system to destroy the existing tumor. Tumors treated with Regressin™ have a low incidence of recurrence. The primary advantages of utilizing this technology are that no general anaesthetic is necessarily required and tumor recurrence in treated animals is significantly reduced.

Procedures for Regressin™

Some types of tumors do not respond to immunotherapy. Therefore, the veterinarian will want to obtain a sample of the animal's tumor. This biopsy will be sent to a laboratory for identification. Following laboratory tests, the consulting veterinarian will be able to provide suitable alternatives for tumor treatment.

When Regressin™ is the procedure of choice, the animal will be admitted to the veterinary clinic for a short stay (1 day or less). The veterinarian will use a local anaesthetic to 'freeze' the area around the tumor, and/or use a mild sedative. Regressin™ will be injected into the tumor following 'freezing' and sedation.

In the week to follow, the animal's tumor will swell slightly and some drainage from the tumor will occur. As the cells of the immune system engage and take action against the tumor cells, the remains of the tumor cells are built up within the tumor itself and thus swelling and drainage occurs. This response is normal and desired. Your veterinarian will be able to offer suggestions on how to manage the drainage at home.

When Regressin™ therapy is used in conjunction with surgical procedures, the first treatment is usually given 2 weeks prior to surgery. Surgery is then performed and subsequent Regressin injections are given to achieve a lower recurrence rate and a longer tumor-free interval.

One of the effects observed following stimulation of the immune system is drowsiness and fever. This, too, is a 'normal' response. The effects will not persist for more than a week. In most cases, the tumor mass must be repeatedly injected with Regressin™. The number of treatments normally should not exceed four. Your veterinarian will likely wish to re-examine your pet on a regular basis to ensure that the tumor does not re-establish.

Summary

Immunology is one of the most rapidly expanding fields in the medical sciences, and the technology of immune stimulating is readily accepted as a means of tumor therapy. BIONICHE Animal Health has brought to the veterinary community the first immunostimulant effective in treating specific tumor types. As a result of this technology, the tumor-free interval following Regressin™ therapy is dramatically increased, compared to surgical methods alone. In addition, Regressin™ therapy is well endured by animals which may not tolerate anaesthetics. Regressin™ immunotherapy for cancer is a viable and cost-effective method of tumor treatment with efficacious results.

US Patent No. 4744984