Immunocidin® Research

Preliminary research indicates that Immunocidin® has great potential for the treatment of multiple cancer types, as well as palliative care.

To discuss extra-label uses of Immunocidin®, veterinarians and veterinary oncologists may contact the NovaVive Technical Department

Mixed Mammary Tumor and Mammary Adenocarcinoma

- *12 dogs enrolled in two treatment groups (6 dogs per group):*

Group 1: *6 female dogs diagnosed with mixed mammary tumor*

- *Tumor size range:* *8 cm^3 to 210 cm^3*
- *Average # treatments:* *3.8 Injections*

Results:

- *5 of 6 dogs achieved 100% remission with intratumoral injection*
- *1 of 6 dogs achieved 80% remission with surgical excision of tumor*

Group 2: *6 female dogs diagnosed with mammary adenocarcinoma*

- *Tumor size range:* *0.05 cm^3 to 21.9 cm^3*
- *Average # treatments:* *3 injections*

Results:

- *1 unrelated treatment death*
- *5 of 6 dogs achieved 100% remission*
- *1 of 5 dogs (prior to unrelated death) achieved 58-60% regression of multiple tumors*

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NovaVive
An immunobiology company

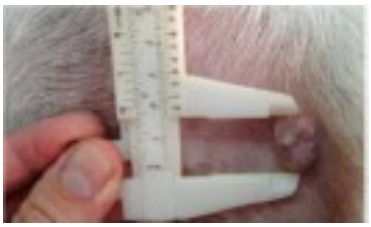
Immunocidin® Research

Mast Cell Tumor (Mastocytoma) (NovaVive – data on file)

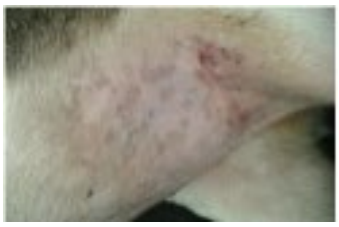
- *Teko: Male, Brazilian terrier, 13 years, 11.2 kg*
- *4 Immunocidin® intratumoral treatments*

Results:

Pre-Treatment

4th Treatment



Immunocidin® as an Osteosarcoma Treatment Following Appendicular Surgery

(NovaVive – data on file)

- *18 dogs diagnosed with osteosarcoma (OS) were treated with Immunocidin® following appendicular amputation*
- *Immunocidin® was administered intramuscularly (IM):*
  - *Day of surgery and once a week for 4 weeks post-surgery*
  - *Then every 2 weeks for the next 3 months*

Results:

- *This study demonstrated that Immunocidin® treatment following surgery has a beneficial effect in dogs diagnosed with OS*
- *Survival rate was 50% at 36 months post-diagnosis in localized OS patients (n=12)*
- *Survival rate was 50% at 12 months in patients with locally invasive OS and/or regional lymph node involvement (n=6)*

Immunocidin® for Transitional Cell Carcinoma (NovaVive – data on file)

- *5 dogs with transitional cell carcinoma of the lower urinary tract were enrolled*
- *Dogs presented with tumors that were recurrent, surgically unresectable, failed chemotherapy, and the owners had declined standard care of treatment*
- *All dogs were treated with Immunocidin® administered intravesically as solo therapy*
- *A dose of Immunocidin® was administered weekly for 4 treatments to 3 dogs*
- *2 dogs received 1 dose on 3 consecutive days, followed by 1 treatment every 14 or 28 days*

Results:

- *3 dogs achieved stable disease status*
- *2 dogs achieved partial remission*

Immunocidin® for Salivary Gland Carcinoma: A Case Study (NovaVive – data on file)

- *1 dog was diagnosed with poorly differentiated salivary gland carcinoma; previous treatments included 3 surgical interventions in combination with chemotherapy*
- *After the 3rd recurrence, Immunocidin® was introduced as a stand-alone treatment*
- *Immunocidin® was administered IT on a weekly basis*

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Results:

- *After 2 IT injections of Immunocidin®, a 10% reduction in tumor size and the stabilization of the disease were observed*
- *2 additional administrations of Immunocidin® contributed to tumor partial response (PR) characterized by progressive tumor ulceration and flattening*
- *6 additional weekly Immunocidin® treatments were performed until complete remission was observed*

Immunocidin® for Lymphoma: A Case Study **(NovaVive – data on file)**

- *Dog with histologically confirmed multicentric lymphoma without evidence of metastasis and enlarged lymph nodes*
- *Treatment regimen included weekly administration of Immunocidin® IV (slow-drip method)*

Results:

- *Survival time is 5 months (2 more than the average median survival rate for standard lymphoma protocols that include chemotherapy)*
- *There are no signs of metastasis, lymph nodes are of normal size and good quality of life is being observed*
- *The patient continues to receive Immunocidin® weekly as of end of 2015 trial*

IV Safety Study with Immunocidin®

J. Kelly, DVM, DACVIM – presented at ACVIM Forum, June, 2018

- *Diluted Immunocidin® administered through IV to dogs and cats with various malignancies showed that the product is safe to administer via this route*
- *The study enrolled 44 patients (40 dogs, 4 cats)*
- *A total of 157 Immunocidin® IV treatments were administered*

Results:

- *Minimal adverse events (mild lethargy or fever) were observed in 5 dogs*

Retrospective Study with Immunocidin® in Lymphoma and Osteosarcoma

J. Kelly, DVM, DACVIM – presented at VCS Annual Conference, October, 2019

- *12 dogs (8 with lymphoma and 4 with osteosarcoma) were analyzed*
- *All dogs received diluted Immunocidin® at the same time as chemotherapy*
- *Lymphoma patients received 6 treatments on average*
- *Osteosarcoma patients received 15 treatments on average*

Results:

- *Dogs with lymphoma survived from 135 days (4.4 months) to 1,246 days (40.9 months)*
- *Dogs with osteosarcoma survived from 104 days (3.4 months) to 653 days (21.5 months)*
- *Adverse events were mild*

Immunocidin® Research

Immunocidin® in Conjunction with Cisplatin as an Osteosarcoma Treatment (NovaVive – data on file)

- *8 dogs diagnosed with osteosarcoma (OS) were treated with Immunocidin® in conjunction with the alkylating agent Cisplatin and appendicular amputation*
- *Beginning 48 hours post-amputation, patients received:*
  - *6 IV doses of Cisplatin (70 mg/m^2) every 4 weeks (slow-drip method)*
  - *Immunocidin® IV once every week during the first 4 weeks (single bolus method)*
  - *Immunocidin® administered in conjunction with Cisplatin afterwards until the end of the treatment period*

Results:

- *Survival rate of 87.5% after 6 months*
- *Disease-free survival rate of 50% 12 months post-surgery*

Effect of Immunocidin® as an Adjunct to Chemotherapy in the Treatment of Transmissible Venereal Tumors (TVTs)

Study 1

- *17 dogs with TVT confirmed by cytology*
- *Vincristine (chemotherapy) was administered 2 times, 7 days apart*
- *Immunocidin® was administered by IV injection once a week for 4 weeks*
- *First 2 Immunocidin® administrations were concurrent with chemotherapy*
- *The last 2 Immunocidin® doses were administered as a solo therapy*

Results:

- *Immunocidin® had a beneficial effect and significantly reduced the use of Vincristine*
- *Immunocidin® increased the complete response rate (100% complete response 29 days post-initial treatment)*

(A)

(A) Left: TVT immediately after 1st Immunocidin® administration

(A) Right: TVT after 3rd Immunocidin® administration

(B)

(B) Left: TVT immediately after 1st Immunocidin® administration

(B) Right: TVT after 4th Immunocidin® administration

Study 2

- *84 dogs with histopathologically confirmed TVTs (including lymphadenopathies) were involved in a comparative study to evaluate non-surgical treatment options for TVTs*
- *The study involved 5 treatment groups:*
  - *I. Vincristine (0.5 mg/m^2, IV once a week) (11 dogs)*
  - *II. Vincristine (0.8 mg/m^2, IV once a week) (46 dogs)*
  - *III. Vincristine (0.5 mg/m^2, IV once a week) plus cyclophosphamide plus methotrexate (11 dogs)*

IV. *Vincristine (0.8 mg/m^2, IV once a week) plus concurrent intratumoral (IT) injection of Immunocidin® (10 dogs)*
V. *Immunocidin® (IT, once a week) (6 dogs)*

Results:

- *The decreased production of neutrophils (neutropenia) caused by chemotherapy was not observed in dogs treated with Immunocidin®*
- *Recommended treatment regimens: IV, V*
  - *Vincristine (0.8 mg/m^2, IV once a week) plus 2 or 3 doses weekly IT injection of Immunocidin®*
  - *For tumors 3 cm^3 or less in size, 3 doses of Immunocidin® (IT) once a week*

Amelioration of Chemotherapy-Induced Neutropenia

Masic, Mangieri, Prunic and Rodrigues, World Veterinary Cancer Congress, May, 2016

- *50 dogs enrolled in study (5 treatment groups of 10 dogs each)*
- *All groups treated with Vinblastine 3 mg/m^2 IV*
- *4 groups also treated with Immunocidin® IV:*
  - *50 µg/kg*
  - *100 µg/kg*
  - *200 µg/kg*
  - *500 µg/kg*
- *Immunocidin® treatment 24 hours post-neutropenia diagnosis*

Results:

- *Days to recovery with Immunocidin® 500 µg/kg: 1 day*
- *Days to recovery with Immunocidin® 200 µg/kg: 2 days*
- *Days to recovery with Immunocidin® 100 µg/kg: 3 days*
- *Future indication: Immunocidin® as an aid in the prevention and treatment of neutropenia following concurrent administration of Vinblastine and Immunocidin® in tumor-bearing dogs*