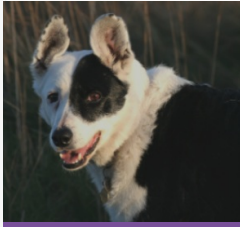


# ONCOALESCE



## Monograph

#1 June 2022

## Greetings!

Dear Greetings!

### Cancer - Climbing the mountain alone?

Welcome to the first edition of the  
Oncoalesce Monograph.

Oncoalesce is a new company whose aim is to increase the communication amongst veterinary oncologists in order to provide everyone with a summary of new products or services, as well as the opinion of a trusted panel of your peers, on the potential benefits of incorporating new products into the clinics. It is hoped this new tool will help all of the profession as **together**, we climb the mountain that is cancer treatment.

This is a VERY long document. I will be producing one every 6 weeks. It should get shorter over time. I hope you find some time to look through it and it serves to answer some of the common questions facing all oncologists.

**Tariq**

Photo: Smith Rock State Park, . Bend, Oregon



Email me!

## Background (read this once)

Due to an increasingly hectic workday, Oncologists have difficulty keeping up with all of the new developments. They can struggle to reconcile what a company may be promoting when compared to the limited data available. They may want to try something new but don't have the time to work out the logistics, or the specific benefits of adjusting their approach. "There is no data" is a common refrain when in actual fact there IS data, we just don't know it yet. Trust is a valuable thing and when looking for supportive information we tend to trust our friends and our peers the most.

Oncoalesce brings together oncology companies (pharma, diagnostics, and services) with a panel of oncologists. They will meet remotely on a regular basis every 6 weeks to discuss how the profession can best adopt and grow the new products that industry is increasingly introducing to the world of veterinary oncology. The panel consists of open-minded clinical oncologists who are prepared to ask: "How SHOULD we use this product?". The companies and the panel explore the claims, compare experiences, ask questions, and come to a consensus of how that product may best be utilized to benefit the patients in our care. Following the meeting, the minutes are transcribed into a succinct monograph that outlines the consensus and provides guidelines for your colleagues. Finally, they are shared freely with all oncologists in an easily digestible format to help guide your own clinical approach.

The aims of Oncoalesce:

- 1 Coalesce – to come together to form one body or whole: The coalition of veterinary oncology – working together in a partnership to achieve a common goal.
- 2 To improve the communication understanding and adoption of new technologies within veterinary oncology.
- 3 To accelerate the use of these technologies to improve the lives of our patients and to encourage the introduction of other companies into the oncology arena.

The following notes have been taken directly from the first **four-hour** Zoom meeting between a panel of oncologists and the companies represented. They contain direct quotes from the panel as well as the answers provided to them by the companies.

Finally, the notes have been edited and added to by the panel post-meeting and represent a true version of their understanding at the time.

It is important to note some views presented here are made by individual oncologists but are not necessarily representative of the whole group.

Conflict of Interest: All members of the panel were paid for their time by Oncoalesce at an industry acceptable hourly rate. They were not paid any other monies and act independently from the companies represented.

Panel:

- Dr. Kim Cronin - MA Veterinary referral hospital
- Dr. Pamela Jones - QBiotics
- Dr. Kendra Lyons - In-between
- Dr. Melissa Parsons-Doherty – Pearland Animal Cancer and Referral Center
- Dr. Erin Roof – Animal Cancer Care Clinic
- Dr. Aarti Sabhlok – Ethos Pet Emergency and Specialty Ctr Marin
- Dr. Andrew Vaughan – Las Vegas Veterinary Specialty Center
- Dr. Rachel Venable - Pet Cancer Care Consulting

#### Companies

- Elias Animal Health
- Imprimed
- Canine Biologics
- Elanco
- Vidium Animal Health
- Jaguar Animal Health

There are at least 24 companies with an active presence within veterinary oncology. I hope over time more companies will be represented through Oncoalesce and will use this platform to provide clinically relevant information for you to be able to trust and adopt.

## The Discussions



Elias Animal Health: Changing how veterinarians treat cancer by being a trusted cancer specialist improving treatment outcomes through advancements of innovative immunotherapies and adjunct therapies.

ECI - Elias Cancer Immunotherapy or VACT – Vaccine primed Adoptive Cell Therapy

Step 1 – Custom vaccine stimulates cancer-specific immune response

Step 2 – Apheresis to harvest mono-nuclear cells

Step 3 – Expand MNC ex-vivo and infuse large numbers of activated T cells to deliver cancer killing payload

Initial trial Amputation + ECI: MST = 415 days (Amputation alone = 134 days)

17 Apheresis hubs so far across America, more to come

59 Oncology hospitals now offering ECI

Finishing off 100+patient pivotal trial. Safety data – very well tolerated. Efficacy data due soon.

Further research is being conducted on an Oncolytic Virotherapy.

#### Panel Experience

“Elias are very easy to work with, very receptive to questions and concerns and very responsive. The step-by-step training program was very nice and invaluable for the doctors and the staff”

Questions – Utility of combining immunotherapy with chemotherapy? This has been done a few times in human medicine - Is this something that Elias has been working on? Elias are unlikely to do a clinical trial soon, but they have also seen some good anecdotal outcomes when carboplatin has been administered before ECI and will support this approach. They can freeze the vaccine for up to 4 months before use.

Comments – previous studies have shown immunotherapy cases can relapse but have extended survivals with a good quality of life even with regression of their metastases which was also seen with the ECI. This was an argument against adding chemotherapy *after* immunotherapy: When dogs relapse after chemotherapy they tend not to have prolonged survival. Therefore chemotherapy may not lend improvement but

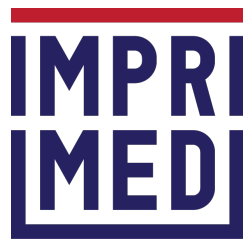
may hinder the immunotherapy benefit in those patients.

Positioning Elias against SOC when talking to owners pre-amputation: “Some clients find it and ask, sometimes I offer carboplatin plus ECI, for some I offer it as one more option. Clients are happy to travel a few hours for apheresis – it is an “all-day thing”.

“There are a lot of moving pieces, organizing apheresis and getting surgeons on board...?” – how can this be streamlined? Elias work closely alongside the oncologist to coordinate and support the oncologist. They also will do webinars for GPs in the area to encourage referrals.

In one hospital - for surgeons who are “too busy”, the proactive oncology techs work with the surgery service and help to harvest and package the tissue for them.

Learn more about  
Elias



### ImpriMed – Artificial Intelligence driven personalized medicine for pet cancer care using a live cancer cell sensitivity assay

The ImpriMed Chemosensitivity assay is a tool that includes comprehensive diagnostic information and drug response predictions for canine lymphoma which can help veterinarians provide personalized treatment care plans for each patient. The machine learning for the Artificial Intelligence stems from over 2900 canine lymphoma treatment cases over four years; the assay is now on version FOUR. Over 8,200 tests have been ordered to date. Flow cytometry and PARR are also run with the assay or can be ordered separately (including Fridays for Saturday processing).

Data presented at the 2022 midyear VCS showed that the dogs that receive the highest 3 recommended treatments have an increased overall response rate ( $p=0.013$ ) and an increased complete response rate ( $p=0.19$ ) compared to dogs that received lower recommendations ( $n=66$ ).

As they did initially with dogs, they are providing free feline phenotyping in return for research samples.

A case history was presented and showed the assay predicted a good but brief response to CHOP, then a second assay predicted a good and long response to Tanovea, in concordance with the clinical experience.

#### **Panel Experience:**

“Impressed with the data they provided”

“I Possibly used it too late to make a big difference”

“I have used the assay both at the beginning and in relapsed cases– Often it predicted CHOP, but sometimes it would provide a different approach which was useful. It was most helpful in relapsed cases. I use Imprimed in atypical naïve presentations or where the dog has relapsed early to guide me e.g. Tanovea or CCNU”.

“Useful in a T-cell, in one case guiding towards CHOP, in another towards Tanovea with both providing successful outcomes”

“Most (but not all) translated into protocols that were effective”.

“Imprimed is not effective in all patients. In my experience about 25% of patients do not respond as indicated by the report. Is there a way to get a number from the company?” – Imprimed report data from an in-depth analysis of one hospital who used the service extensively. Out of 28 patients with full adherence to recommendations and where records and follow up information were available, 23 reports correlated with the patients’ clinical outcome (82%). Furthermore, this was taken from the 2020 assay and performance since then has been improved considerably.

One hospital promotes it up front in order to use the best drugs first. They offer to all patients, and it is “overall relatively accurate”. It is better than “throwing numbers at clients”

Comments – More data is required for a deeper dive into specific lymphomas e.g. teasing out indolent lymphomas or different grades to guide towards chronic daily chlorambucil v CHOP: The database is so far not able to do this, but it is something they are working on as their caseload of these rarer lymphomas grow. In addition, most of the learning has been on 25week CHOP protocol; in time they may be able to provide additional information on 25wk v 19 wk.

In answer to a great question – sequential assays run on the same dog do demonstrate a change in results when sensitivities alter over time; sometimes the sensitivity remains consistent over time when a drug rated “high” to start with has not yet been used.

It is worth noting – If there are enough cells in the sample, they will provide an assay on all 13 drugs. Listing preferential drugs is only used if fewer cells are available for the assay. In addition, recent advancements in the assay now enable fewer cells to be used for each drug allowing more drugs to be tested each time.

[Learn more about Imprimed](#)



### Canine Biologics

Founded to develop specialized nutritional support specifically for dogs with cancer. Cancer patients are undergoing a complete and permanent metabolic reprogramming requiring higher levels of protein and fat. This is more than a lifestyle choice. Human grade (safe for human consumption) food ensures the highest quality nutritional value, digestibility and palatability, freeze dried to preserve quality whilst ensuring convenience. Separate wild Alaskan salmon oil supplies a rich source of omega 3 fatty acids whilst ensuring maximum quality without the risk of oxidation. The supplement mix incorporates vitamins, minerals, amino acids and plant extracts providing maximum, tailored support.

This whole area was summed up in a great comment:

The potential for this is absolutely enormous – every client asks what should I feed my dog? And if there is science behind it, then it is something clients will jump all over, and be very excited, but we need more science and we need randomized trials. We need to

demonstrate a better quality of life; they're going to gain weight, they're going to have better body condition, they're going to tolerate chemo, they're going to live longer.... Without this are we any further ahead than we were 20 years ago? Is a potential benefit the same as an actual benefit?

**Response:**

The supplements have demonstrated an actual benefit in different clinical trials and using as much of an evidence-based approach as possible, this data fed into the formulation. Secondly – we are not a drug, and it would be so difficult and complex and expensive to do an FDA type trial. Having said this, it is in their plans to do some studies including the measurement of muscle mass using ultrasonography techniques with NC State. The system is not a treatment for cancer, but it will provide the cancer patient with the energy they need and the optimal nutrition they need to help them battle their cancer. The formulation follows the recommendation from a board-certified nutritionist who has dedicated years of (published) research to work on a solution to help dogs with cancer and this diet specifically answers many of her concerns.

Ultimately, dogs need to eat, and if an owner is looking for a solution and seeing a nutritionist is not an option, this is one of the best evidence-based solutions out there and is NOT just a lifestyle choice. It is a healthy nutritional choice.

Canine Biologics have further projects on the horizon to support their product and the panel appreciate the difficulty of the entire subject of nutrition and appreciate what CB has done so far.

**Comment:**

“My big feeling is we do not have any other information on cancer diets to provide to clients at this time so this is a great option to try until those studies and data are available”

[Learn more about Canine Biologics](#)



## Elanco

Elanco presented an update on their specialist portfolio, including

- Entyce oral solution, FDA-approved for appetite stimulation in dogs
  - A wide-open label
  - Intervene early; don't wait for weight loss
  - Supportive of chemotherapy induced anorexia and preventing weight loss
  - Stimulates the release of growth hormone, causing the release of IGF-1 which promotes lean body mass growth
- Elura oral solution, FDA-approved for management of weight loss in cats with chronic kidney disease.
  - Showed 3.3% increase in body weight within first 2 weeks, and a 6.8% difference at day 55

- Zorbium – long-acting buprenorphine (opioid) transdermal solution for cats. Indicated for the control of postoperative pain associated with surgical procedures in cats.
- TANOVEA...

### Feedback experience for Tanovea

“I Use Tanovea alternating with Doxorubicin” - having failed CHOP. Some significant skin issues, but rare and the results are worth the risk.

“Originally used Tanovea as a single agent, but after full FDA approval I now pretty much only use it with Doxorubicin”

“I use it a lot, we do see some GI issues – diarrhea and transient anorexia, but this does not preclude its use, rarely any other AE's. It is certainly useful when the use of dox is less applicable, a week or two after vincristine or cyclophosphamide with no issues, it is very useful in B-cell lymphoma and cutaneous lymphoma.

Tanovea with Laverdia as a combination was discussed but no one had experience of this. There is potential for this in the future, with the proviso of the potential combined GI issues. The potential for Tanovea followed by Laverdia as maintenance was also raised.

There was no more to add about use in cats, which everyone wants. The trial is ongoing at UG, looking at dose characterization.

The collaborative subject of Tanovea plus Imprimed as a diagnostic test indicating the use of Tanovea was raised and discussed. The Imprimed assay can predict the positive use of Tanovea single agent, as well as the combined use of Tanovea and Doxorubicin, both in the naïve and relapsed setting.

There was some agreement that an advantage of using Tanovea in the first line setting was the 5-visit v 16 visit protocol, certainly as oncologists are getting even busier, and the potential for Imprimed to guide this choice becomes appealing. Oncologists have been exploring the use of Tanovea in Multiple Myeloma, [If anyone has any feedback on this area of usage, please use the Oncoalesce forum to share the experience. (Email me...)]. One panel member had just started in MM and so far things were going well and the dog had responded. Another member had used 5 cycles of Tanovea to treat cutaneous plasma cell disease (with small cell lymphoma!) and had a good response.

One question for Elanco was regarding Entyce and how some dogs do not like the taste. An off-label recommendation was to use Elura in smaller dogs which has a different formulation, including anti-bittering agents, at the same Entyce recommended dose. One panel member had found the addition of Karo syrup to help palatability. Elanco do not know why geography seems to play a role in the palatability of the drug (maybe the geography dictates the types of dog owners you encounter?).



### Vidium

Vidium curates an extensive biomarker database called Vidium Insight. This database contains information from the published literature on over 1400 known cancer biomarkers found within 360 curated genes, taken from 5000 sequenced tumors in 48 cancer types. The data looks for diagnostic prognostic and therapeutic biomarker associations. Only by having such an extensive, well curated database can you then run a genomic assay and expect the results to be clinically meaningful.

Searchlight DNA is a targeted next-generation sequencing panel drawing from the Vidium Insight database to look for several mutation types covering 120 genes. Sample types



include fresh cytology as well as histology samples.

Now that Vidium offers histology directly utilizing Drs. Barb Powers, Jeff Edwards and Derick Whitley, samples can be submitted for basic confirmatory diagnosis with the easy option to follow up with Searchlight DNA if required. Their multidisciplinary approach combines the pathologist, oncologist and genomicist for a wholesome approach to clinical management.

Reports are provided both in a simple form for the client and a more detailed report for the clinician, including details on therapeutic biomarkers and potential targeted drugs. A free consultation regarding the specific case is also included.

Drug monographs on the main therapies are made available containing canine specific information, but Vidium avoid a potential conflict of interest by not selling recommended drugs directly.

#### **Experience:**

“I’ve used Vidium several times, but the presentation showed me lots of new ways that I can utilize the assay”

“I’ve used several times when SOC has failed, the reports are very thorough, and Vidium have been supportive in developing a plan of action”

“The new pathology team are integrally linked in the whole process and play a valuable role in supporting the clinician on poorly differentiated tumors”

Use in lymphoma cases – “sometimes it has been used when all else has failed (“spin the chemo wheel”) but sometimes it has been used at the beginning to provide other options for treatment”.

#### **Questions**

When you can't easily aspirate a new tumor, how useful is the original biopsy when a fresh sample cannot be taken, especially concerning metastatic disease?

Targeted mutations can change under different treatment pressure so it is always better to take a fresh sample. If you cannot, it is still valuable to look at the original tumor since many of the main truncal driver mutations are still very relevant and rarely change.

You can find mutations, but are these drug-able? – Vidium provides published human and veterinary evidence to support any drug associations. In the absence of druggable mutations on the report (which are based on high evidence levels), they will look for therapies to consider based on first principles and pathway biology (so-called “white-gloving”) at the clinician’s request. For any drug associations (whether reported or white-gloved), they are not prescriptive but rather leave it to the clinician to decide which treatment plan is best based on the clinician’s best judgement of the case in hand.

“I can see how Vidium will be one of my new best friends moving forward. I’ve spoken to their pathologist but never really got a lot of info on Searchlight so there is a lot to learn”.

[Learn more about Vidium's Searchlight DNA](#)



Jaguar Animal Health



Canalevia-CA1 is the only conditionally approved FDA drug for the treatment of chemotherapy-induced diarrhea in dogs. Chemotherapy in this case has been clarified by the FDA to include targeted therapy.

Mode of action – Crofelemer is an inhibitor of two chloride ion channels in the luminal membrane of enterocytes and normalizes the fluid influx into the GI tract.

No serious adverse events have been reported in studies. Crofelemer is safe and well tolerated.

In a pilot study on dogs with acute diarrhea, 9/12 dogs (75%) in the treatment group resolved their diarrhea by day 3, compared to 3/12(25%) in the control group.

Additionally, 4 of the 12 treated dogs had resolved in 48 hours, compared to none in the control group.

Dosing is one 125mg tablet (up to 140lb) twice a day with or without food, for three days. Price per tablet is \$7.89 and is available in bottles of 60 tablets.

Canalevia-CA1 can only be used to treat diarrhea when it occurs and not as a prophylaxis. Its MOA is quite rapid and should be administered as soon as diarrhea is seen i.e. it can be prescribed in anticipation with the indication to use in the event of diarrhea, as long as that is clearly explained to the client.

With the use of ongoing oral precision medicine, when patients exhibit more of a chronic diarrhea, there is no limit to the number of 3-day dose scripts can be written for any one patient. Extended use in trials has demonstrated there are no serious adverse events. However, there is no data to establish if this is necessarily the first choice for chronic diarrhea.

It is worth noting since it was raised – some of the early adverse events reported were using non-enterically coated drug formulations and were not seen subsequently using the Canalevia-CA1 formulation.

#### Thoughts:

“The cost is not the problem; we routinely give Cerenia over metoclopramide and if Canalevia-CA1 holds up clinically, then we will use it”. Others (who also worked within a corporate pricing model hospital) did also confirm cost would not be a problem.

“I’ve now prescribed Canalevia twice and both clients were excited to not have to use an antibiotic such as metronidazole for their pets’ diarrhea”

I do hope Canalevia becomes a major tool to help avoid the indiscriminate overuse of antibiotics.

There are resources available and more information on chemotherapy induced diarrhea on the Canalevia-CA1 website for clients who want to learn more (but you don’t have time to explain). <https://www.canalevia.com/dog-owners>

(More feedback will hopefully be provided over time through Oncoalesce)

Learn more about Canalevia-CA1

## Summary

“These are all very exciting things... we haven’t reached perfection but you have to start somewhere and then see what is working and modify our approach if it isn’t working.... Having companies listen to what we say is

important – we are the ones who are driving the attitudes of GPs so if an oncologist thumbs up, the GPs will be on board too.”

“Having missed VCS for 2 years, now I have a better idea of what products are out there, at a slower pace, where I can ask the tough questions and see how the companies answer them”

“I’m really excited to see what we can get out to the other oncologists – that’s going to be the big thing – we get so much stuff so if we can make it into an easy read and hopefully the more we use these products the more data we will have and the better understanding we will have. “

“We should not be trying these new products in heavily pre-treated cases and then expecting them to work well; often these products in the appropriate setting work very well but they should not be the very last, great things...This applies to Imprimed early use rather than when all else has failed, Canalevia, Tanovea, Entyce etc.

Too often oncologists take the view “well, I have nothing else that will work so let’s give this new drug a try”. It is not really fair to the potential benefits of the test or drug in question”.

Oncoalesce will reconvene in July to discuss any new experiences, or updates. The next Oncoalesce Monograph should be more succinct, but no less useful.



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