

Louie the Beagle surpasses one year on MPL

Highlights

- **Patient in canine trial surpasses 365 days with stable disease and continued excellent Quality of Life (QoL)**
- **MPL extends survival three-fold, to a median of 150 days, while maintaining QoL**
- **PharmAust's commercial strategy aimed at bridging the options of standard-of-care with chemotherapy is on target**

6 July 2023 – Perth, Australia: PharmAust Limited (ASX: PAA & PAAO), a clinical-stage biotechnology company, is pleased to announce a significant milestone for a patient in the Phase 2 trial for the treatment of canine B-cell Lymphoma with Monepantel (MPL).

Louie surpasses one year on MPL

B-cell Lymphoma in dogs has a poor prognosis. Unfortunately, without treatment, many types of lymphoma are fatal within a few weeks. In cases, the veterinarian may advise palliative care (steroid drugs) to reduce symptoms and possibly extend the survival time for a few weeks. However, even though chemotherapy can offer extended survival (typically around 12 months), it is only palliative and often results in an unacceptable adverse events profile and substantial costs.

PharmAust's commercial strategy is to take the middle ground in the treatment of B-cell Lymphoma which is achieved by inducing stable disease for 4-6 months with minimal side effects, so that the family and the dog can enjoy the limited time together.

In PharmAust's current Phase 2 study, a 13-year-old Beagle "Louie", has surpassed 365 days (one year) as a result of being treated solely with MPL, and showing no side effects while his Quality of Life (QoL) remains excellent. Louie was diagnosed with Progressive Disease (PD) at the end of his 28-day trial and despite this poor prognosis, Louie has achieved > 365 days of good quality of life. Thus, it appears that dogs given MPL + prednisolone (or, in Louie's case, MPL on its own) after the 28-day trial period are living three times longer than expected with good quality of life and no chemotherapy-related side effects.

Louie's owner Iain Gibson said Louie still enjoys his walks and "can still manage a decent pace" while sniffing everything in his path,

"Mealtimes are Louie's favourite part of the day and his second favourite thing is cuddles," said Mr Gibson. "Louie also attends doggy daycare two days a week and loves to chill out with his "pack" at home, quite happy doing nothing as long as he has someone to do nothing with."

The Gibson family felt very fortunate the MPL trial was available at the time Louie became ill.

"The trial is 100% the best decision that we could have made for Louie. He deserved a break after the other issues with his knees and spleen he's had over the years. We've so enjoyed this extra time we've had with Louie and hoping that his eventual passing won't be quite so painful as a result of this extra time," said Mr Gibson.

The life expectancy of dogs with B-cell Lymphoma, treated with the standard of care (palliative steroid therapy) typically provides for 42-56 days of survival in association with progression. The combination of MPL with prednisolone has extended median survival to these pet dogs of 150 days. More importantly, owner surveys from dogs in the trial indicate an excellent QoL score feedback.

MPL is already approved for veterinary use for a different indication in food-chain animals. PharmAust is endeavouring to repurpose MPL as a safe and effective cancer treatment without the associated side effects of chemotherapy.

Principal Investigator Dr Kim Agnew stated: “Despite Louie being with Progressive Disease at Day 28, the ongoing MPL therapy has helped to stabilise further development of the lymphoma since that time. The tumour development slowed and, despite Louis still having evidence of lymphoma, his energy and quality of life remain excellent.”

Testimonial from Louie’s owner

Louie is a 13-year-old Beagle and has been a beloved family pet for over 10 years. He’s a very happy dog, loves people, other dogs and life in general.

After Louie had been with us for a couple of years, he had knee issues and had to have both cruciate ligaments operated on. When he was 9 years old, he got sick at Christmas time and ended up having a benign growth and his spleen removed.

In June 2022, we took him to see our local vet as we found some lumps in his neck. Louie was diagnosed with lymphoma and given 4-8 weeks to live.

We were given a couple of treatment options including chemotherapy or steroids. Chemo wasn’t an option for us, and we didn’t like the sound of the side effects of large doses of steroids. For one thing, making a Beagle even more hungry than usual would have been a challenge.

Our vet told us about a drug trial that would possibly suit Louie if we were interested. An appointment was made to take Louie to Veterinary Specialists Aotearoa (VSA) in Auckland for an initial assessment. At the end of the initial visit, we were given an initial prescription of Monepantel and an appointment for a follow up visit in 2 weeks.

Louie took the Monepantel tablets for those 2 weeks with no side effects and just carried on with the normal life of a 12-year-old Beagle. At the 2-week check-up, it was found that Louie’s lymph nodes had shrunk 20% and there were no side effects from the drug.

Louie has had several follow up visits to VSA and at the last check-up, the size of his lymph nodes that can be easily measured have hardly changed since the 2-week measurements were taken.

Louie has continued taking the Monepantel; we are now 12 months on from the initial diagnosis and Louie is still going strong. He’s still enjoying a good quality of life and fingers crossed he still has a little while left yet.

The Monepantel has been a great treatment for Louie as it has extended his life well beyond the initial prognosis with no side-effects and has maintained his quality of life.

Iain, New Zealand



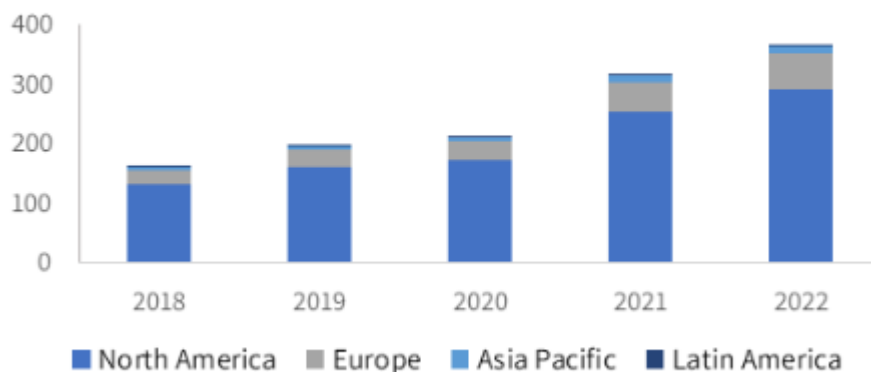
Ease of home therapy to help oral therapeutics gain traction

Pet cancer therapeutics market from the oral route of administration segment is projected to reach a valuation of more than USD 359 million by 2032. Notable developments in oral medicines due to their clinical benefits, including the ease & comfort of home therapy and fewer clinic visits, are bolstering segment expansion. In a recent instance, in May 2022, the FDA granted conditional approval to Laverdia-CA1 or Verdinxor tablets, the first chemotherapy pills for dogs with lymphoma. These pills can induce apoptosis and enrich the antiproliferation of cancer cells for chemotherapeutic agents.

Growing lifespan of dogs to accelerate demand for cancer therapeutics

By species, the pet cancer therapeutics market from the dogs segment exceeded USD 352 million in 2022 on account of the rising penetration and a spike in the occurrences of feline cancer. Moreover, risk factors related to in-breeding and non-purebred dogs have escalated the chances of tumors and lymph. In a recent 2022, the result highlighted improved lifespan of dogs as one of the major reasons for early signs of cancers due to the natural selection of protected pets with enhanced medicines and cures for illnesses. It also concluded that the increasing population of old dogs has increased the cancer ratio worldwide.

Global Pet Cancer Therapeutics Market, By Region, 2018 - 2022 (USD Million)



Source: www.gminsights.com

The Board authorises this announcement.

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About PharmAust Limited:

PharmAust Limited is listed on the Australian Securities Exchange (PAA) and the Frankfurt Stock Exchange (ECQ). PAA is a clinical-stage company developing therapeutics for both humans and animals. The company specialises in repurposing marketed drugs lowering the risks and costs of development. These efforts are supported by PAA's subsidiary, Epichem, a highly successful contract medicinal chemistry company that generated \$3.4 million in sales of goods & services in FY 2022.

PAA's lead drug candidate is monepantel (MPL), a novel, a potent and safe inhibitor of the mTOR pathway – a pathway having key influences in cancer growth and neurodegenerative diseases. MPL has been evaluated in Phase 1 clinical trials in humans and Phase 2 clinical trials in dogs. MPL treatment was well-tolerated in humans, demonstrating preliminary evidence of anticancer activity. MPL showed objective anticancer activity in dogs. PAA is uniquely positioned to commercialise MPL for treating human and veterinary cancers and neurodegenerative diseases as it advances a reformulated version of this drug through Phase 1 and 2 clinical trials.

