QBiotics Group
NATURALLY INSPIRED

NEWS RELEASE

QBiotics receives first registration for tigilanol tiglate with European Medicines Agency approval of Stelfonta®

- STELFONTA® (tigilanol tiglate) approved by the European Medicines Agency (EMA), making it the first pharmaceutical treatment available for all grades of canine non-metastatic mast cell tumours (MCT)[1]
- The approval marks the first registration of QBiotic's, lead compound tigilanol tiglate, which is also under review by the US Food and Drug Administration - Center for Veterinary Medicine (FDA-CVM) and the Australian Pesticides and Veterinary Medicines Authority (APVMA);
- Approval is supported by a full technical data package focused on safety and efficacy including a pivotal study in 123 canine patients where a single injection of STELFONTA® completely removed (Complete Response) 75% of treated MCT;[2]
- QBiotics have partnered with Virbac, who will be launching STELFONTA® across key EU markets in the coming months.

Brisbane Australia, Monday 20 January 2020 – Australian life sciences company, QBiotics Group Limited (QBiotics) is today announcing the first registration for its small molecule, tigilanol tiglate, with the European Medicines Agency (EMA) approval of STELFONTA as an oncology veterinary pharmaceutical.

STELFONTA (tigilanol tiglate) is indicated for the treatment of non-resectable, non-metastatic (WHO staging[3]) subcutaneous MCT located at or distal to the elbow or the hock, and non-resectable, non-metastatic cutaneous MCT in dogs. Tumours must be less than or equal to 8 cm^3 in volume and must be accessible to intratumoural injection.[1]

MCTs are the second most frequent cancer diagnosed in dogs and the most common skin cancer, accounting for up to 21% of skin cancer cases.[3]

QBiotics Veterinary Oncologist, Dr Pam Jones said "The EMA approval of STELFONTA represents an exciting additional treatment option for MCT where surgical removal of the tumour mass is currently the standard of care.[4] However, there are some challenges associated with surgery, as in some cases the tumour isn't always easily accessible, and anaesthesia carries inherent risks - especially for older dogs and brachycephalic breeds.

"STELFONTA is administered by injection directly into the tumour mass. Generally, dogs undergoing treatment do not need to be sedated, or need local or general anaesthesia," said Dr Jones.

Worldwide, as many as 1 in 4 dogs will develop cancer at some time in their lives. Cancer is the leading cause of death in dogs, with almost 50% of dogs over the age of 10 years dying of the disease.[5,6]

"To date, there are only a very small number of registered treatments for cancer in companion animals, providing a significant opportunity for new treatments in this growing market," said QBiotics' CEO and Managing Director, Dr Victoria Gordon.

"Tigilanol tiglate is a new approach to the problem of cancer. The drug works largely through specific protein kinase C (PKC) activation, in which it locally stimulates the immune system, resulting in destruction of the

tumour mass and the tumour's blood supply, followed by rapid healing of the site with minimal scarring,"[7] Dr Gordon said.

Approval for STELFONTA was based on a full data package supporting the safety and efficacy of STELFONTA. This included a QBiotics sponsored, pivotal, multi centre, randomised, blinded and untreated control study in 123 canine patients with MCTs. This study was conducted in accordance with the principles of Good Clinical Practice (GCP) as outlined in 'Guidance for Industry Guideline #85 of the USA Food and Drug Administration (FDA), Center for Veterinary Medicine Good Clinical Practice: VICH GL9, Final Guidance May 2001.

In this pivotal study conducted in eleven veterinary clinics, at 28 days post treatment 75% percent of dogs achieved a Complete Response (tumour is completely destroyed) after a single intra-tumoural injection of STELFONTA compared to untreated controls (*p=0.0001*). Importantly, STELFONTA® was very well tolerated and animals had a good quality of life during and after treatment.[2]

Dr Gordon said "QBiotics and our partner, global veterinary pharma company Virbac, are gearing up for the launch of STELFONTA in early 2020, initially in the UK, France, Spain and Germany, and later in the USA, subject to FDA approval. This is an exciting time for QBiotics, adding global commercialisation of a novel pharmaceutical to our list of attributes."

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ABOUT QBIOTICS

QBiotics is a public unlisted Australian life sciences company which discovers, develops and commercialises novel anticancer and wound healing products for human and veterinary markets.

Its lead product, tigilanol tiglate, is an anticancer pharmaceutical targeting a range of solid tumours across multiple species.

QBiotics' business model is to develop products that have application in both veterinary and human markets. Success in the veterinary programs validates QBiotics technology and de-risks human development, while generating early, non-diluting revenues.

REFERENCES

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