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COMPLETION OF QBIOTICS USA VETERINARY ANTI-CANCER TRIAL IN USA TREATING DOGS WITH MAST CELL TUMOURS

Study completes data package for FDA & EMA submission

- In the completed USA veterinary pivotal clinical study of QBiotics' anticancer pharmaceutical tigilanol tiglate (EBC-46), shows 75% of the cases met the protocol defined 'Complete Response' (full tumour destruction) criteria after a single injection when treating dogs with mast cell tumours (MCT),
- The drug was reported to be well tolerated by patients with owner-stated good quality of life both during and after treatment,
- This field safety and effectiveness multi location trial is the final section of the QBiotics data package for regulatory submission.
- QBiotics plans to submit final applications in October 2018 for assessment by the Food and Drug Administration – Centre for Veterinary Medicine (FDA-CVM) and European Medicines Agency (EMA) which, if successful, will lead to market authorization for tigilanol tiglate as a veterinary pharmaceutical for canine MCT.

Australian life sciences company, QBiotics Group Limited (QBiotics) has received positive top line results from its core pivotal field safety and efficacy clinical trial in dogs with mast cell tumours, using anticancer pharmaceutical tigilanol tiglate (EBC-46).

The eleven-site, multicenter, fully blinded and sham (untreated) controlled field study evaluated the full tumour destruction (Complete Response) rate in 123 dogs with MCTs, 28 days after receiving a single injection into the tumour with tigilanol tiglate (EBC-46). The Complete Response, following a single injection, was calculated at 75% compared to 5.3% in the control group.

Adverse events (negative effects) and owner-provided quality of life measures were also assessed during and after treatment. Tigilanol tiglate was reported to be well tolerated by patients with pet owners stating good quality of life both during and after the study.

These core field safety and efficacy trial results are the final section of QBiotics' data package required for submission for registration of tigilanol tiglate as a veterinary pharmaceutical to the FDA and the EMA in October 2018.

Dr Victoria Gordon, QBiotics CEO and Managing Director said: "We are very pleased with the outcomes of this major veterinary study as they are consistent with the levels of safety and efficacy demonstrated in previous Australian studies.

"Our objective is to gain registration and marketing approval in the United States and Europe, followed by Australia and other major regions," Dr Gordon said.

Clinical trial progress

Tigilanol tiglate has demonstrated anticancer potential in a range of solid tumours in over 400 companion animals (dogs, cats and horses).

The USA clinical trial focus has been on dogs with mast cell tumours. Following completion of initial field safety and efficacy veterinary clinical trials in Australia, this pivotal efficacy registration trial in 123 dogs in the USA has now been completed.

Application for registration of tigilanol tiglate as a veterinary pharmaceutical in the USA will be via the FDA-CVM. The centralised European Medicines Agency (EMA) route will be taken for European veterinary registration of the drug, which will enable marketing authorisation for tigilanol tiglate in all 28 EU countries. Application for registration in other regions, including Australia, will then follow.

Cancer in dogs

Worldwide as many as 1 in 4 dogs will develop cancer at some time in their lives, and almost 50% of dogs over the age of 10 years will die of the disease.[1,2] Mast cell tumour is the most common cutaneous cancer in dogs accounting for 16 to 21% of all cutaneous canine cancers.[3,4]

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.

Mode of action

Tigilanol tiglate works through specific protein kinase C (PKC) activation, in which it locally stimulates the immune system resulting in destruction of the tumour mass as well as the tumour's blood supply, followed by rapid healing of the site with minimal scarring.[5]

Studies have demonstrated that tumour destruction usually occurs within 5-7 days with the site fully healed within approximately 4-6 weeks.[6,7]

In addition to destruction of the tumour, added benefits of the drug as identified in the clinical trials include potential avoidance of limb amputation in the case of limb located tumours and minimal scarring of treatment site supporting return to normal mobility.

Tigilanol tiglate administration is by injection directly into the tumour mass. Generally, treatments with the drug do not require the use of sedation, or local or general anaesthesia. In general, clinically observed actions of the drug are as expected due to the mode of action of tigilanol tiglate on tumour destruction. These actions include transient, localised swelling and moderate pain for the first few days.

Other QBiotics progress

QBiotics' commercial strategy is to bring tigilanol tiglate to major veterinary markets to create cash flow for further development of QBiotics technology in human cancers and wound healing.

QBiotics has recently completed a first- in-human clinical trial of tigilanol tiglate in patients involving four Australian hospitals. This Clinical Phase I/IIA safety study is in the final stages of report writing. Results from this trial are planned for submission to a peer reviewed global scientific journal for publication as well as presentation at global pharmaceutical industry conferences. QBiotics is in the process of commencing a Human Clinical Phase IIA trial treating head and neck cancer with tigilanol tiglate.

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ABOUT QBIOTICS

QBiotics is an Australian life sciences company which discovers and develops novel bioactive compounds derived from the Australian tropical rainforest using proprietary discovery technology EcoLogic™. QBiotics has a pipeline of other products in development addressing wound healing, dementia and microbial infections. The company uses its strength in veterinary pharmaceutical development to support and inform their human programs. QBiotics' commercial strategy is to launch products into veterinary markets to provide cash flow for development of therapies for human applications.

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