QBiotics Group
NATURALLY INSPIRED

AGREEMENT UPDATE **9 AUGUST 2018**

QBIOTICS SIGNS MARKETING, SUPPLY AND DISTRIBUTION AGREEMENT WITH VIRBAC FOR CANINE CANCER TREATMENT

- QBiotics and Virbac have signed a marketing, supply and distribution agreement for a new canine anticancer drug, tigilanol tiglate
- Mast cell tumour pivotal efficacy registration trial has been completed for registration in the USA, Europe and the UK
- Final submission to the USA FDA-CVM and European EMA for tigilanol tiglate is planned for October 2018 followed shortly by other regions including the APVMA in Australia

Australian life sciences company, QBiotics Group Limited (QGL), has signed an agreement with Virbac, one of the largest dedicated animal health companies globally, to market and distribute its canine anticancer pharmaceutical, tigilanol tiglate.

Under the terms of the agreement, Virbac is granted the right to market and distribute tigilanol tiglate, QBiotics' anticancer pharmaceutical, to veterinary markets in the USA, Switzerland, Norway, UK and EU on receipt of marketing authorisation. There is the potential of future expansion to other focus territories including Australia, New Zealand and Canada.

The initial term of the agreement ends in 2025. It can be extended for another eight years.

The agreement includes milestone payments and a split of revenue received by Virbac in addition to payments that increase over time and vary based on revenue thresholds.

Tigilanol tiglate is a new approach to the treatment of solid tumour cancers, discovered by applying QBiotics' EcoLogic™ approach to drug discovery.

Dr Victoria Gordon, QBiotics CEO and Managing Director said: "This agreement is a significant milestone for the company. We believe Virbac is the right partner for us to launch tigilanol tiglate in key international markets. Virbac has the expertise and global footprint to maximise the commercial success of tigilanol tiglate in major regions such as the USA and Europe. In addition, they join in QBiotics' passion about the potential of tigilanol tiglate to address canine cancer for veterinary practitioners, dogs and their owners. Together with Virbac, we have now commenced the launch preparation for the drug."

Sébastien Huron, chairman of the executive board of the Virbac group said: "With aging dogs and only a small number of registered treatments for cancer in companion animals, there is a significant opportunity for new treatments in the veterinary market globally. Mast cell tumors (MCTs) or mastocytomas are the most common cutaneous tumor found in dogs, accounting for 16-21% of all cutaneous tumors. We were impressed with QBiotics' platform technology, EcoLogic™ using compounds derived from the Australian tropical rainforest to identify astonishing drugs such as tigilanol tiglate, and we look forward to working with the QBiotics team to launch this innovative product in the USA, UK and EU before expanding to the rest of the world."

Clinical trial progress

Tigilanol tiglate has demonstrated anticancer potential in a range of solid tumours in over 500 companion animals (dogs, cats and horses).

The USA clinical trial focus has been on dogs with mast cell tumours. Following completion of initial safety and efficacy veterinary clinical trials in Australia, the pivotal efficacy registration trial in over 120 dogs in the USA has now been completed.

It is expected that drug will be registered under the FDA-CVM in the USA. 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 with all 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]

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.[3]

Studies have demonstrated that tumour destruction usually occurs within 5-7 days with the site fully healed within approximately 3-4 weeks.[4,5]

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 a simple injection directly into the tumour. Generally, treatments with the drug do not require the use of local or general anaesthetics. The only main side effects of the drug are a function of its tumour destruction action, resulting in localised and transient 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.

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[1] Kelsey JL, *et al.* (1998) Epidemiological studies of risk factors for cancer in pet dogs. Epidemiology Review 20 (2):204-217.

[2] Withrow SJ. and Vail DM. (2007) Small Animal Clinical Oncology, Elsevier Inc, Canada 402-421.

[3] Boyle G et al. 2014. Intra-lesional Injection of the Novel PKC Activator EBC-46 Rapidly Ablates Tumors in Mouse Models, PLOS ONE, Vol 9, Issue 10

[4] Lowden S 2017. Tigilanol tiglate (EBC-46), a new tool in the anti-solid surface tumours tool box?

[5] Barnett C et al. Optimising intratumoral treatment of head and neck squamous cell carcinoma models with the diterpene ester Tigilanol tiglate. Investigational New Drugs; April 2018

QBiotics has recently completed a proof of concept human clinical trial of tigilanol tiglate in patients involving four Australian hospitals. This Clinical Phase I/IIA safety trial 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 now planning the Human Clinical Phase IIA trial for tigilanol tiglate.

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ABOUT QBIOTICS - https://qbiotics.com/

QBiotics is an Australian life sciences company which discovers and develops novel bioactive compounds derived 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.

ABOUT VIRBAC - https://corporate.virbac.com/home-en.html

Focusing on animal health, from the beginning

Founded in 1968 by a French veterinarian, Virbac is an independent pharmaceutical laboratory dedicated to animal health, since its beginning. Currently the world's 7th largest animal health company and present in more than 100 countries, Virbac offers a comprehensive and practical range of products and services covering the majority of species and pathologies. Virbac innovation, based on both technological advances and listening to its customers, relies on production facilities which meet the highest international quality standards. For fifty years, these features have allowed the company to build a personalized relationship with veterinarians, farmers and pet owners around the world. Through these privileged partnerships, in which social, health and environmental issues come together, Virbac contributes, day after day, to shape the future of animal health.