QBiotics doses first Australian patient in Phase I/II Clinical Trial for Head and Neck Cancer

BRISBANE, QLD, AUSTRALIA, July 22, 2020 /EINPresswire.com/ -- QBiotics Group Limited (QBiotics), a life sciences company developing novel small molecule anticancer and wound healing pharmaceuticals, is pleased to announce that it has dosed its first Australian patient in its Phase I/II clinical trial evaluating the optimal dose and safety of lead molecule, tigilanol tiglate, in patients with head and neck squamous cell carcinoma (HNSCC).

> We hope that with tigilanol tiglate, we might be able to bring a much□needed new treatment to patients who currently have few other options."
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> *Dr Victoria Gordon, Managing Director and CEO, QBiotics*

Dr Victoria Gordon, Managing Director and CEO of QBiotics, said, "We are delighted to have treated our first Australian patient under this trial and to be working with such world class investigators as Associate Professor Richard Gallagher and his team at the Kinghorn Cancer Centre, a joint facility of St. Vincent's Hospital and the Garvan Institute of Medical Research. This milestone marks important progress in our QB46C□H03 study, and our third clinical site treating patients, along with the Tata Medical Centre in Kolkata, and the Tata Memorial Hospital in Mumbai, India."

Surgery is currently the mainstay for HNSCC, however, in many cases the tumours are unresectable (unable to be removed by surgery), can be disfiguring, or patients may be too unwell for surgery. Therefore, there is a significant need for new treatments that can remove unresectable tumours, especially in the head and neck region, to preserve a person's appearance, as well as critical functions such as sight, hearing, speech and swallowing. Tigilanol tiglate is administered directly into the tumour mass, which limits exposure and damage to surrounding healthy tissues, and reduces the risk of functional or cosmetic impairment as well as reduced systemic toxicity.

Dr Gordon continued, "Cancers of the head and neck are challenging and frequent, with more than two million1 new cases each year. We hope that with tigilanol tiglate, we might be able to bring a much□needed new treatment to patients who currently have few other options."

Associate Professor Richard Gallagher, Head and Neck Surgeon, Principal Investigator of The

Kinghorn Cancer Centre site commented “This is a very exciting trial using a unique technology discovered and developed in Australia. Every surgeon wants to avoid destructive surgery which can compromise a patient's quality of life. So a simple intratumoural injection is a very appealing advance. If successful in head and neck cancer, this research may have the potential to benefit cancers across the spectrum of disease."

The Phase I/II open label “QB46C□H03” study, is a dose escalation study in patients with HNSCC, designed to determine the maximum tolerated dose and recommended dose level for further studies. The study will also investigate safety, tolerability and tumour response following a single or multiple (two to three) doses of tigilanol tiglate. It follows QBiotics’ successful first□in□human QBC46□H01 study2 in a range of solid tumours, which demonstrated patients with squamous cell carcinoma, the most common type of head and neck cancer, had encouraging tumour responses when treated with tigilanol tiglate.

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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.
https://qbiotics.com

ABOUT TIGILANOL TIGLATE

Tigilanol tiglate is a small molecule that is being tested as an intratumoural treatment for solid tumours. Its effect on tumours is multimodal and involves injected tumour responses

as well as distal responses in non-injected tumours. Complete destruction of the injected tumour is mediated via tumour vascular disruption as well as death of tumour cells by oncosis3. Following tumour destruction, rapid wound healing has been shown to ensue.

A single injection of tigilanol tiglate has been shown in canine patients to ablate (completely destroy) 75% of treated tumours4. Veterinary use of tigilanol tiglate (branded STELFONTA®) has recently received marketing authorisation by the European Medicines Authority as a treatment for canine mast cell tumours. STELFONTA® is also under review by the US Food and Drug Administration - Center for Veterinary Medicine, and by the Australian Pesticides and Veterinary Medicines Authority. STELFONTA® is partnered with Virbac, a global animal health company and launched in Europe in April 2020.

ABOUT THE KINGHORN CANCER CENTRE

The Kinghorn Cancer Centre is a joint venture between St Vincent's Hospital Sydney and The Garvan Institute of Medical Research and combines scientific and medical expertise to treat cancer patients.

Bringing together researchers and clinicians onto a single site, The Kinghorn Cancer Centre enables research findings to be rapidly translated into clinical application for the diagnosis, treatment and prevention of cancer.
http://tkcc.org.au/

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