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NEWS RELEASE **TUESDAY 3 DECEMBER 2019**

QBIOTICS ANNOUNCES FIRST PATIENT DOSED IN ITS PHASE I/II CLINICAL TRIAL OF TIGILANOL TIGLATE FOR HEAD AND NECK CANCER

- First patient successfully dosed in QBiotics' Phase I/II clinical trial of tigilanol tiglate in patients with Head and Neck Squamous Cell Carcinoma (HNSCC)
- Tigilanol tiglate is a novel, small molecule that is being tested as a single injection treatment for solid tumours
- The Phase I/II clinical trial is a dose escalation study in HNSCC patients designed to determine optimal dosage, safety and tumour response
- The QBC46-H03 trial is being run in Australia and India.

BRISBANE, 3 December 2019. QBiotics Group Limited (QGL), a life sciences company developing novel anticancer and wound healing pharmaceuticals, today announced that it has dosed its first patient in a Phase I/II clinical trial evaluating the optimal dosing and safety of its lead product, tigilanol tiglate, in patients with head and neck squamous cell carcinoma (HNSCC).

Dr Victoria Gordon, Managing Director and CEO of QBiotics, said, "We are delighted to announce the treatment of our first patient in our multi-site clinical study, which includes trial sites in Australia and India. Cancers of the head and neck rank as the sixth most common cancer diagnosed worldwide[1] with more than 2 million[2] new cases each year. The high rate of HNSCC is largely driven by tobacco use, and increased infection with human papillomavirus (HPV)."

Dr Gordon continued, "This study marks an important advancement for QBiotics' oncology pharmaceutical. It follows our successful first-in-man QBC46-H01 study[3] 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."

Surgery and radiotherapy are currently the primary local treatments for HNSCC. However, these treatments can come with challenges such as damage to healthy tissue and impacting a person's ability to breathe, hear, see, smell, swallow or taste as well as adversely affecting appearance. Better local therapies are therefore needed. Direct intratumoural injection with tigilanol tiglate may offer advantages as it directly targets tumour cells and reaches infiltrating cancer cells that can be missed by surgery. This approach limits exposure and damage to surrounding healthy tissues, reducing the risk of functional or cosmetic impairment. Intratumoural injection also offers the potential for reduced toxicity due to localised (target site) treatment, compared to systemic toxicity induced by chemotherapeutic agents.

[1]Union for International Cancer Control (UICC), WHO Essential Medicines List. https://www.who.int/selection_medicines/committees/expert/20/applications/HeadNeck.pdf (accessed 26 November 2019).

[2] Globocan, 2018. Sum of lip, oral cavity, larynx, hypopharynx, salivary glands, nasopharynx and oesophagus based on ICD-10 codes.

[3] Panizza, B. et al., 2019. Phase I Dose-Escalation Study to Determine the Safety, Tolerability, Preliminary Efficacy and Pharmacokinetics of an Intratumoral Injection of Tigilanol Tiglate (EBC-46). EBioMedicine: in press.

The Phase I/II open label "QBC46-H03" study, is a dose escalation study in patients with HNSCC aimed at determining the maximum tolerated dose (MTD) 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 will enrol up to 40 patients from the Tata Medical Centre in Kolkata, the Tata Memorial Hospital in Mumbai, the Princess Alexandra Hospital in Brisbane, and other clinical sites in Australia.

Ends#

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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 novel, small molecule that is being tested as an intratumoural injection treatment for solid tumours. Its effect on tumours is multimodal and involves direct local effects on the injected tumour as well as effects on distal, non-injected tumours. Complete destruction of the injected tumour is mediated via tumour vascular disruption as well as death of tumour cells by oncosis. 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 tumours[4]. Veterinary use of tigilanol tiglate (branded STELFONTA®) has recently received a majority vote by the European Medicines Authority (EMA) for marketing authorisation in Europe as a treatment for canine mast cell tumours, and is also under review by the US Food and Drug Administration - Center for Veterinary Medicine (FDA-CVM) for marketing in the USA. STELFONTA® is partnered with Virbac, a global animal health company for marketing and distribution in the EU and USA pending regulatory approval. Launch of the product is expected early 2020 in both regions.

[4]Data on file.