QBiotics Group
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NEWS RELEASE **EMBARGOED TUESDAY 10, DECEMBER, 2019**

PUBLICATION OF FIRST IN-HUMAN DATA REVEALS SAFETY & EFFICACY OF TIGILANOL TIGLATE IN SOLID TUMOURS

- First in-human Clinical Phase I study of intratumoural tigilanol tiglate (EBC-46) has been published in The Lancet's EBioMedicine journal;
- An efficacious dose was achieved and a Maximum Tolerated Dose (MTD) was not reached, indicating tigilanol tiglate tolerability in humans;
- Promising outcomes attained in patients with a variety of solid tumour types, with a 27% treatment response, including 18% complete response (full tumour destruction);[1]
- Following these positive results, a Phase I/II trial of tigilanol tiglate in patients with Head and Neck Squamous Cell Carcinoma (HNSCC) is underway, with the first patient successfully dosed.

Australian life sciences company, QBiotics Group Limited (QBiotics) is today announcing the publication[1] of positive results from a first in-human Phase I clinical trial of its anticancer pharmaceutical, tigilanol tiglate (EBC-46) in EBioMedicine, a peer-reviewed translational biomedical research journal by The Lancet.

The key objectives of this Phase I, open-label, single-arm, non-randomised, dose-escalation study were to determine the safety profile, tolerability, pharmacokinetics (PK), and preliminary antitumour efficacy of tigilanol tiglate when administered once by intratumoural injection. Tigilanol tiglate was generally well tolerated and doses escalated from 0.06 to 3.60 mg/m^2, without reaching a maximum tolerated dose.

The study was conducted in 22 patients at four hospital sites in Australia[1]. Patients were recruited with a range of tumour types including squamous cell carcinoma, basal cell carcinoma, melanoma, breast adenocarcinoma, atypical fibroxanthoma, atypical myxoid fibrosarcoma, metastatic colorectal adenocarcinoma, adenoid cystic carcinoma and angiosarcoma. Signs of clinical activity were observed in all nine tumour types, even at the lowest doses.

"As this was a first-in-human, single dose safety study, the expectation of a strong anticancer response was low. However, the results revealed a 27% treatment response (in 6 patients), including an 18% complete response (in 4 patients) with full tumour destruction across a wide variety of solid tumour types.

"Solid tumours account for up to 80% of all tumour types,[3] so the results from this Phase I study indicate potentially broad applications for tigilanol tiglate in a range of tumours, and an important advancement for our pharmaceutical," said QBiotics Group CEO and Managing Director, Dr Victoria Gordon.

"Additionally, two patients with melanoma demonstrated an anenestic (or abscopal) response, where non-injected tumours at different locations in the body also reduced in size. These results were achieved despite many patients not receiving an optimal dose,[1]"added Dr Gordon.

The vast majority (96%) of adverse events (AEs) were mild to moderate, with the most commonly reported AE being injection site reaction related to the mode of action of tigilanol tiglate. AEs were generally managed with symptomatic therapy.[1]

"Given the very good safety profile, and positive antitumour responses observed, this study supports further development of tigilanol tiglate as a potential treatment of solid tumours," said Dr Gordon

"Results from this study also underpins selection of our initial lead indication and our recently announced Phase I/II trial of tigilanol tiglate in patients with Head and Neck Squamous Cell Carcinoma (HNSCC), in which the first patient was successfully dosed last week," Dr Gordon said.

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 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, and other clinical sites in Australia.

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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 small molecules 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 human and veterinary markets. Success in the veterinary programs validates QBiotics' technology and de-risks human development, while generating early, non-diluting revenues.

More information: https://qbiotics.com

ABOUT TIGILANOL TIGLATE

Tigilanol tiglate is a novel, small molecule undergoing development 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.

References

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2. Squamous cell carcinoma, melanoma, basal cell carcinoma, breast adenocarcinoma, atypical fibroxanthoma, atypical myxoid fibrosarcoma, metastatic colorectal adenocarcinoma, adenoid cystic carcinoma and angiosarcoma
3. Dunn, B., Cancer: Solving an age-old problem. Nature, 2012. 483(7387): p. S2-6.
4. QBiotics Group Ltd., Data on file. 2019.