

## **QBiotics ANNOUNCES POSITIVE RESULTS WITH FIRST IN-HUMAN STUDY OF TIGILANOL TIGLATE IN SOLID TUMOURS**

- First in-human Clinical Phase I/IIA safety study of tigilanol tiglate (EBC-46) shows promising results in patients with a variety of solid tumour types, supporting a broad potential application of the pharmaceutical,
- The study was concluded when an efficacious dose was achieved without a Maximum Tolerated Dose being reached, thus providing an early indication that tigilanol tiglate is well-tolerated in humans,
- These promising results support QBiotics' intention to move forward with a Human Clinical Phase IIA efficacy trial with the anticancer pharmaceutical tigilanol tiglate.

Australian life sciences company, QBiotics Group Limited (QBiotics) has received positive results from the first in-human Phase I/IIA clinical trial of its anticancer pharmaceutical tigilanol tiglate in patients with solid tumours. The study was conducted across four Australian hospitals.

The first in-human Phase I/IIA clinical trial evaluated the dose-escalation, preliminary efficacy, and pharmacokinetics of intratumoural tigilanol tiglate in patients with cutaneous, subcutaneous, head and neck or nodal tumours.

Results from the safety and tolerability study indicated intratumoural tigilanol tiglate was well tolerated, as a Maximum Tolerated Dose for the drug was not reached, and signs of clinical efficacy were identified in nine different tumour types including Complete Response (full tumour destruction) achieved in 2 patients. These positive results support QBiotics' plans for a Clinical Phase IIA efficacy trial.

QBiotics Group CEO and Managing Director, Dr Victoria Gordon, said: "Results from the Clinical Phase I/IIA trial with tigilanol tiglate indicate the potential of our drug as a well-tolerated anticancer treatment with application across a range of solid tumour indications. These results are an encouraging step forward in the treatment of solid tumours in humans, and support our advancement with a Clinical Phase IIA efficacy trial," said Dr Gordon.

"Findings from the Clinical Phase I/IIA study with tigilanol tiglate are impressive for a first in human trial. No Maximum Tolerated Dose reached and signs of clinical efficacy across nine different tumour types certainly encourages further development of the drug," said Dr Gordon.

### **Mode of action**

In non-clinical pharmacology studies, tigilanol tiglate has been shown to have multiple inter-related effects that are responsible for its anticancer efficacy. Within the first few hours of treatment there is an oncolytic effect on tumour cells resulting in mitochondrial swelling and tumour cell membrane destruction. At the same time, tigilanol tiglate activates specific isozymes of protein kinase C (PKC) resulting in increased permeability of the tumour vasculature leading to tumour vascular destruction. A localised inflammatory response is also induced recruiting and activating innate immune cells (principally neutrophils and macrophages), which then target the tumour mass and release reactive oxygen species, proteases and cytokines that function in an antimicrobial role. This acute inflammatory response generally resolves within 2-3 days. Full tumour destruction usually occurs within 4 to 7 days of treatment. Healthy granulation tissue then rapidly fills the newly-created wound bed with full wound closure occurring typically within 4 to 5 weeks.<sup>1,2,3</sup>

### Other QBiotics progress

Results from the in-human Clinical Phase I/IIA safety study are now 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.

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 US Food & Drug Administration – Center for Veterinary Medicines (FDA-CVM) veterinary pivotal field efficacy study of tigilanol tiglate treating dogs with mast cell tumours. This fully blinded and sham (non-treated) controlled safety and efficacy multi-location trial was the final section of the QBiotics regulatory data package.

QBiotics submitted an application to the European Medicines Agency (EMA) early October and plans to submit an application to the FDA-CVM and the Australian Pesticides and Veterinary Medicines Authority (APVMA) before the end of the year. If these applications are successful, they will lead to market authorisation(s) for tigilanol tiglate as a veterinary pharmaceutical for canine MCT.

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### ABOUT QBOTICS

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™. In addition to the anticancer pharmaceutical tigilanol tiglate, QBiotics is also developing a wound healing treatment for chronic and acute wounds and has early discovery programs in 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.

### References

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