



**QBiotics Group**

Harnessing the power of  
nature to improve lives

**SACHS IO FORUM 2023**

E: [Richard.Godfrey@qbiotics.com](mailto:Richard.Godfrey@qbiotics.com)

W: [qbiotics.com](http://qbiotics.com)

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# QBiotics – at a glance



## EcoLogic™

- Translating ecological knowledge into novel therapeutics
- Megadiverse tropical rainforest
- Phenotypic screening
- Unique Molecular Scaffolds
- Unencumbered IP
- Parallel develop therapeutics for human & companion animal markets



## Focused Strategy

### Oncology

- Tigilanol tiglate IT
- Solid tumors

### Wound healing

- EBC-1013 topical gel
- Venous leg ulcers
- Equine wounds

Strong patent position for both programs

Early stage programs:  
**Antibiotics**  
**Anti-inflammatory**



## Regulatory & Commercial validation

- **STELFONTA®** (tigilanol tiglate) registered and marketed for treatment of canine mast cell tumors
  - 75% CR rate in FDA registration trial
  - >15,000 dogs treated in EU, USA, UK and Australia
  - Robust compliant supply chain



## Human Oncology

- **Phase II** trial in patients with head and neck cancer (QB46C-H08)
- **Phase II** trial in patients with soft tissue sarcoma (QB46C-H07)
- Parallel translational research program

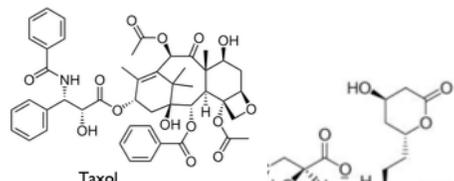


## Organisation

- Strong scientific knowledge
- In-house veterinary capabilities
- Secure raw material growing facilities
- Revenue and strong Balance sheet
- **Seeking partners to accelerate development & commercialization**

### Why go back to nature as a source of new drug scaffolds?

Produced in nature = demonstrated compatibility with the cellular environment

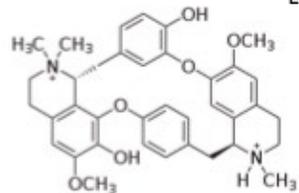


- 45% marketed pharmaceuticals are based on small molecules discovered in nature

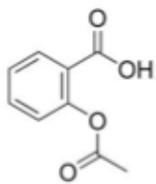
- Remarkable chemical diversity unmatched by synthetic chemistry

- Selected by evolution to engage protein binding sites, for interactions with membranes, and to function at ambient temperatures:

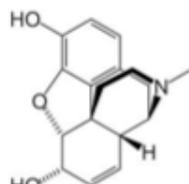
- Features which suggest high potential for effective novel drug compounds



Tubocurarine

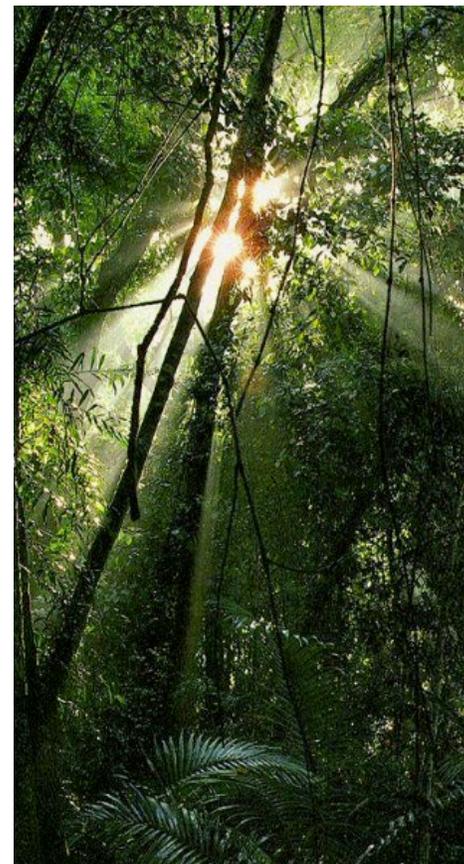


Aspirin



Morphine

### Why Tropical Rain Forests?



- Contain more than half of the world's species
- Complex interactions between species and with the physical environment drives chemical innovation in the quest for survival
- EcoLogic™ employs an understanding of rainforest ecology to help decode the chemical language of the forest and guide our search for new therapeutics for human and animal health
- Collection ownership ensured by agreements that are in line with the UN Convention on Biological Diversity & the Nagoya Protocol

# R&D Pipeline of novel therapeutics for human and veterinary

	Therapeutic Area	Lead Molecule	Trial ID	Indication	Stage of Development				
					Pre-clinical	Phase I	Phase II	Phase III	Registration / Marketing
Human	Oncology	Tigilanol tiglate	QB46C-H03 ACTRN12619001407189	Head & Neck Cancer	Phase I/IIa reporting				
			QB46C-H08 NCT05608876	Head & Neck cancer	Phase II recruiting				
			QB46C-H07 NCT05755113	Soft Tissue Sarcoma	Phase II pilot recruiting				
	Wounds	EBC-1013		Venous Leg Ulcers	Phase I/II				
				Other Wounds	Veterinary models				
Veterinary	Oncology	Tigilanol tiglate	Species & Indication		Clinical			Registration / marketing	
			Canine - Mast Cell Tumor		STELFONTA® – marketed EU, UK, USA and Australia				
			Canine - Soft Tissue Sarcoma & Oral melanoma		STELFONTA® – Phase IV trials				
	Equine - Sarcoid & melanoma		STELFONTA® – Phase IV trials						
	Wounds	EBC-1013	Equine & Canine - Acute/Chronic wounds		Veterinary clinical case studies				
Discovery			Target		Collection	Lead Optimisation			Initial Pre-clinical
	Antibiotics		Multiple Resistant Organisms						
	Anti-inflammatories		Dermatology						



# Human Oncology

tigilanol tiglate  
*Lead Molecule*



# tigilanol tiglate

**Potential in early  
and late settings**

**Effective against  
a range of solid  
tumors – ‘pan-  
tumor potential’**



**Regulatory and  
Commercial validation  
in veterinary market**

**STELFONTA®** (tigilanol tiglate) registered and marketed for treatment of canine mast cell tumors in USA, UK, EU & Australia as a **1L alternative to surgery**

Full tumor destruction (75% CR) from a **single IT injection**

Partnered with Virbac, global animal health company



**Robust, compliant & commercial global supply chain is well established**

**Substantial pre-clinical evidence**

**Single injection**, rapidly destroys tumors and induces systemic immunity via

- Tumor vascular disruption & tumor cell oncolysis
- Immunogenic cell death
- Induces anesthetic responses

Substantial improvement in overall survival compared to standard of care therapies

Strong patent portfolio

**Phase I study complete  
Phase II trials underway**

**Phase I** - Well tolerated; minimal AEs

Clinically relevant activity observed in **9 tumor types**

Impressive rapid wound healing for therapeutic and cosmetic benefits

**Phase II  
Head and neck cancer**

**Soft tissue sarcoma**

**Significant Growth Opportunities**

Very effective & well tolerated ‘pan-tumor’ small molecule  
Potential for development in multiple cancers:

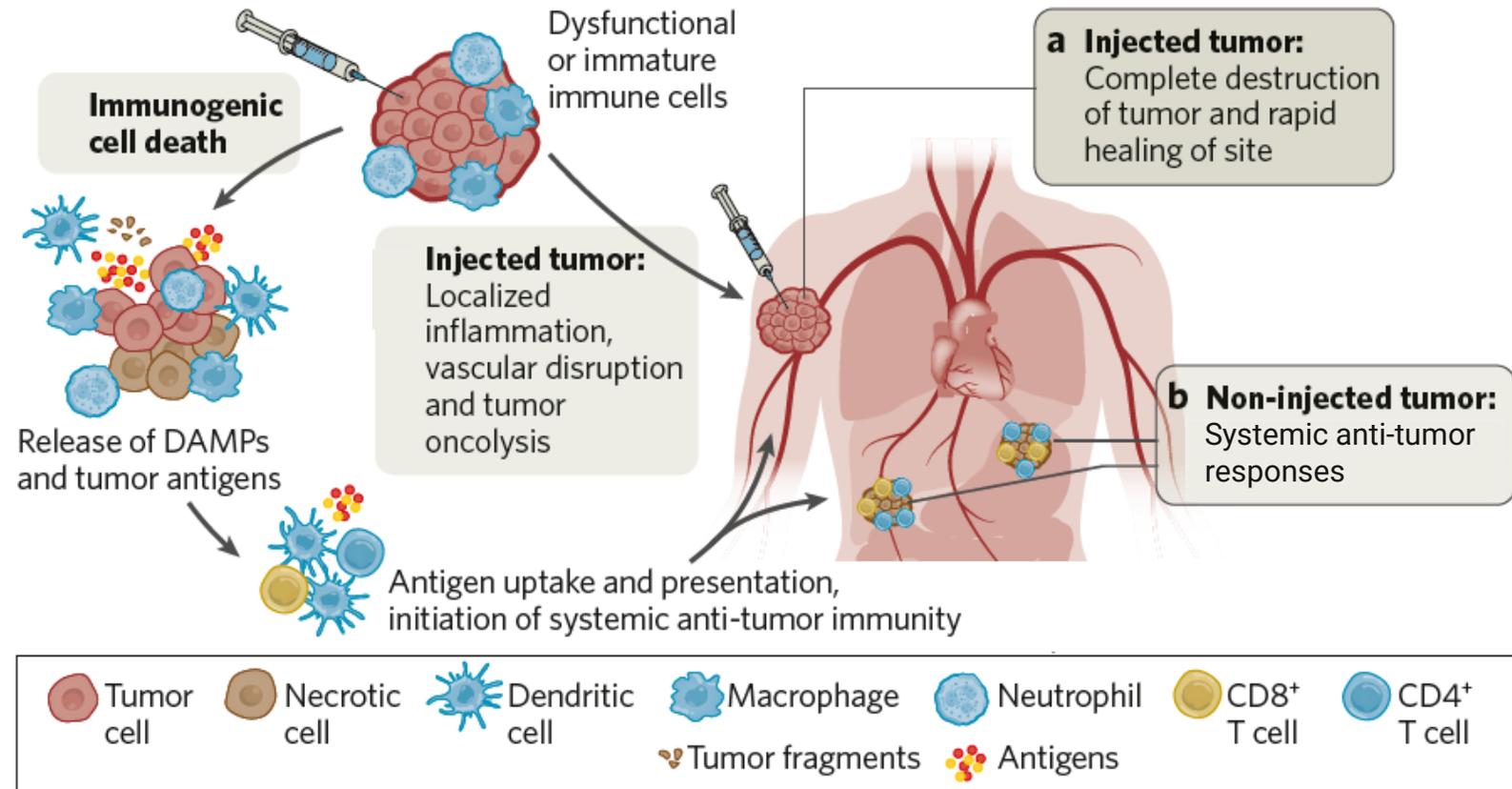
- Monotherapy
- In combination with ICI, chemotherapy etc
- Neoadjuvant
- Alternative or adjunct to surgery

**Seeking license or collaboration to further develop tigilanol tiglate - deal agnostic**



# Tigilanol tiglate acts locally through tumor cell killing and vascular disruption, and systemically through anti-tumor immunity

- ✔ Reduces tumor volume & increases survival in syngeneic murine models
- ✔ Induces systemic anti-tumor responses
- ✔ Induces long-term, durable protection against tumor re-challenge



[www.nature.com/biopharmdeal](https://www.nature.com/biopharmdeal) | March 2022



# Clinical Development Path for tigilanol tiglate

## Pre-clinical

- ✓ Single agent efficacy in range solid tumors
- ✓ Single agent efficacy in metastatic models
- ✓ Substantial improvement in overall survival compared to standard of care therapies
  - ✓ Combines with anti-PD1 in CPI refractory metastatic models
  - ✓ Synergises with chemotherapy
  - ✓ Synergises with radiotherapy

## Veterinary

- ✓ **STELFONTA®** (tigilanol tiglate) registered and marketed for treatment of canine mast cell tumors
- ✓ 75% CR rate in FDA registration trial
- ✓ >15,000 dogs treated in EU, USA, UK and Australia
- ✓ Robust compliant supply chain
- ✓ Canine more relevant to human cancers – spontaneous tumors, relevant histology & genetics & relevant response to treatment

## Phase I complete

### Design:

Open-label, dose escalation (3+3) of a single intra-tumoral injection of tigilanol tiglate in 22 patients

### Population:

Accessible cutaneous, subcutaneous or nodal solid tumors refractory to conventional therapy, or patient choice

**Primary objective:** Safety and tolerability  
**Secondary objectives:** PK, injected tumor response (RECIST 1.1) at 21 days post injection

**Dose:** 0.06 to 3.6 mg/m<sup>2</sup> BSA

- ✓ **Nine tumor types**
- ✓ **Safe and well tolerated**
- ✓ **No MTD but optimal dose identified**
- ✓ **Clinically relevant response in 20/22 pts**
- ✓ **4 CR, 3PR, 14 SD**
- ✓ **At optimal dose - 4/6 CRs, 6/6 local tumor control (CR/PR/SD)**

## Phase IIa on going

### Head and Neck

#### Squamous cell carcinoma (HNSCC)

*Advanced & locally advanced disease with few options*

**ACTRN12619001407189**

**QB46C-H03**  
Phase I/II  
Exploratory

*Reporting*

#### Solid malignancies

*Advanced & locally advanced disease with few options*

**NCT05608876**

**QB46C-H08**  
Phase II

*Recruiting*

### Sarcoma

#### Soft tissue (various stages)

*Heterogeneous disease with few options*

**NCT05755113**

**QB46C-H07**  
Phase II  
Exploratory

*Recruiting*



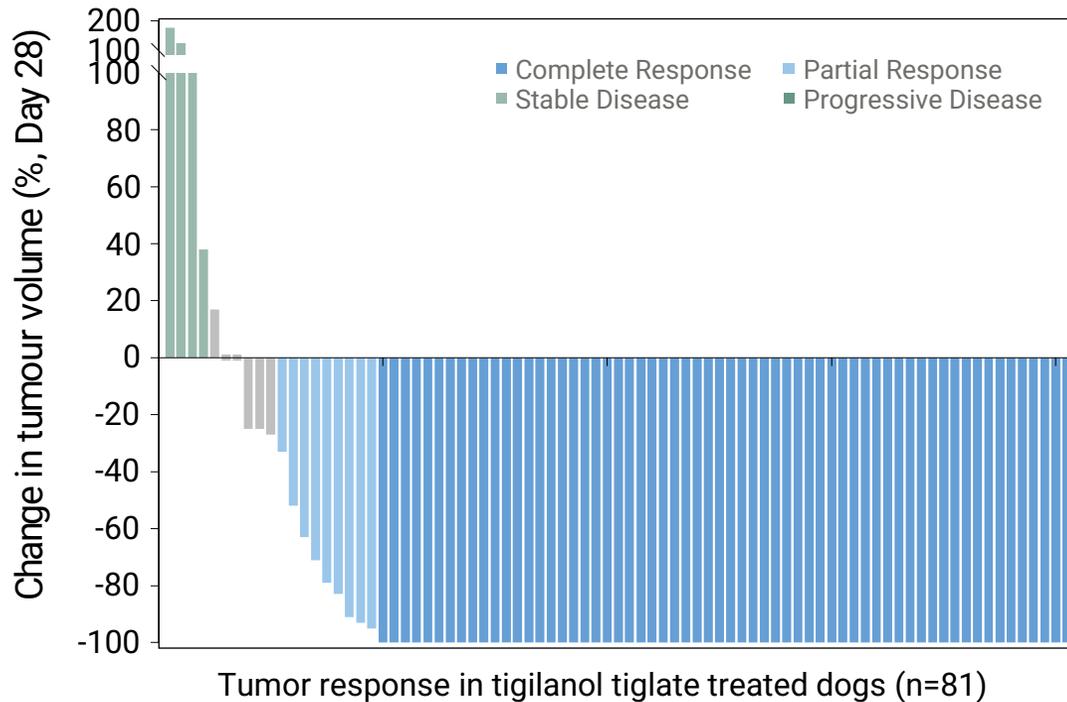
Memorial Sloan Kettering  
Cancer Center



# US FDA-CVM Registration trial for tigilanol tiglate

A single treatment induces Complete Responses in 75% canine mast cell tumors

## Tigilanol tiglate monotherapy – US FDA-registration trial Optimal Dose Rate



## Clinical case from US FDA-CVM registration trial



Day 0: Pretreatment



Day 1: tumor haemorrhagic necrosis



Day 7: tumor destroyed (CR)



Day 28: Site healed

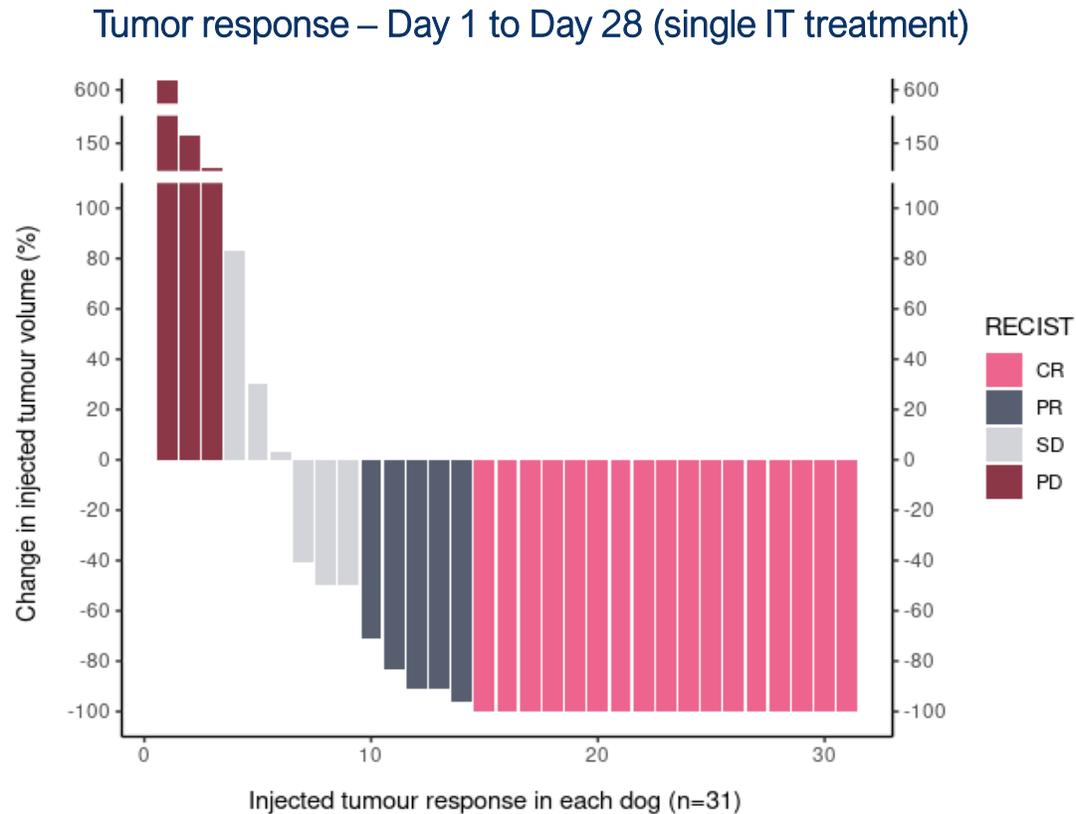
- ✓ 75% CR with a single IT treatment ( $p < 0.0001$  vs sham control)<sup>1</sup>
- ✓ **Objective Tumor Response Rate (CR/PR) of 80%**
- ✓ 88% CR with a second treatment for partial responders. No tumor recurrence in 89% of evaluable cases (n=57) at 12 months<sup>2</sup>

1. Study Report PN1894. Published by [De Ridder T. et al \(2020\)](#).  
2. [Jones et al., 2021](#).



# Canine Clinical Trial of Soft Tissue Sarcoma (STS)

A single treatment induces Complete Responses in 50% STS



✓ 50% CR with a single treatment of tigilanol tiglate ( $p=0.0021$  vs sham control)<sup>1</sup>

✓ Objective Tumor Response Rate (CR/PR) of 61.9%<sup>2</sup>

✓ No tumor recurrence in 89% of evaluable cases ( $n=9$ ) that had CR at 84 days post-treatment.

✓ Rapid and clean wound healing

1. Study Report QB46C-C12 (PN1956). Waterfall plot includes sham treated dogs treated with tigilanol tiglate at Day 30, and then evaluated at Day 28 post injection.  
2. RECIST v1.1 applied to injected Target tumor<sup>2</sup>.



# Canine Case Study

Single treatment led to a Complete Response in Soft Tissue Sarcoma

**12 yr Poodle Cross**

**Histogenesis:**

Grade 1 Soft tissue sarcoma

**Treatment:**

Tumor Vol: 6.25 cm<sup>3</sup>

Single IT injection

**Result:**

Complete Response



Day 0: Pretreatment



Day 3: Haemorrhagic necrosis



Day 6: Complete Response, good granulation of site



Day 44: Site fully healed



Day 261: No tumour regrowth

# Soft Tissue Sarcoma:

Complete response with a single injection of tigilanol tiglate<sup>1</sup>

- Patient had failed surgery
- Difficult to treat lesion, patient initially advised a total rhinectomy

## Pt 407 - Soft Tissue Sarcoma (Angiosarcoma)

- Tumor size: 5,141 mm<sup>3</sup>
- Single IT treatment at optimal dose rate



Pretreatment



Day 2: vascular disruption and haemorrhagic necrosis of tumors



Day 15: tumor necrosis continues



Day 43: Complete Response<sup>2</sup>

- ✓ **Complete Response & Organ Preservation**
- ✓ **No residual tumor** at 12 weeks (punch biopsy)<sup>1</sup>
- ✓ Patient **disease free** (CT scan) at 25 months and **clinically disease free at 30.5 months**<sup>1</sup>
- ✓ **Tigilanol tiglate well tolerated**; AEs mild and transitory

<sup>1</sup>Phase I Clinical Study Report QB46C-H01 and Panizza et al., 2019. EBioMedicine

<sup>2</sup>Reported off study by Panizza et al., 2019. EBioMedicine

# Squamous Cell Carcinoma:

Complete response with a single injection of tigilanol tiglate<sup>1</sup>

- Patient had failed earlier radiotherapy and chemotherapy treatments<sup>1</sup>

## Pt 202 - Squamous Cell Carcinoma on cheek

- Tumor : 200 mm<sup>3</sup>
- Single IT treatment at optimal dose rate



Pretreatment



Day 1: Vascular disruption and haemorrhagic necrosis of tumors



Day 5: Tumor necrosis continues



Day 8: Tumor necrosis continues



Day 15: Complete Response

- ✓ Complete Response at Day 15, with no scarring
- ✓ **Tigilanol tiglate well tolerated**; AEs mild and transitory

*Phase I Study Report QB46C-H01 and published by Panizza et al., 2019. EBioMedicine*

<sup>1</sup>Patient had received prior treatment with radiotherapy, cetuximab, cisplatin and 5FU (> 7 months prior to treatment with tigilanol tiglate)



# Metastatic melanoma

Complete response in injected and non-injected tumors with a single dose of tigilanol tiglate

## Pt 102 - Multiple melanoma

Single IT treatment into top 3 tumors (1,200 mm<sup>3</sup>) at optimal dose rate 4<sup>th</sup> tumor (circled) not treated



**Day 1: Pretreatment**

4 tumors on upper arm

**Day 1: 30 minutes post:**

Vascular disruption and hemorrhagic necrosis of tumors

**Day 3: Necrotic tumors slough**

**Day 8: Non-injected, 4<sup>th</sup> tumor (circled) regresses**

**Day 29: Complete Response in injected and non-injected tumor. Injected sites healed.**

**Lung & sternum tumor regressed - reported off study<sup>1\*</sup>**

Phase I Study Report QB46C-H01 and published by Panizza et al., 2019. EBioMedicine  
1. Panizza et al., 2019. EBioMedicine  
\*. Patient received prior treatment with RT and pembrolizumab 2 months prior to administration of tigilanol tiglate



# A Phase II, open label, single arm study (QB46C-H08) to assess the efficacy of intratumoral tigilanol tiglate in various head and neck solid malignancies (NCT05608876)

Head and neck cancer is the **7<sup>TH</sup> most common** cancer worldwide

**~932,000** new cases each year<sup>1</sup>



## Unmet need

Unresectable  
Locally advanced  
Recurrent/Metastatic disease



Total Market Value **\$US 5.2 billion** by 2030)<sup>2</sup>



>108,000 patients unresectable head and neck tumors

## Patient Population

- Adults with recurrent and/or metastatic head and neck cancer
- $\geq 1$  measurable lesion by ultrasound ( $\pm$ CT or MRI) accessible for intratumoral injection (cutaneous, subcutaneous)
- ECOG PS  $\leq 2$
- Allow unresectable & resectable tumors
- Allow CPI-experienced and prior systemic treatments

## Tx1 Phase

Tigilanol tiglate intralesional ( $\leq 3.6$  mg/m<sup>2</sup> BSA)

## Additional Treatments Tx2 to Tx5

Residual Tx1 Tumour

OR

Additional tumours

Surgery

OR

Up to total of 5 repeat injections of TT to be given Q4W per tumour

Determination of tumor ablation rate

Total n=37 patients

Simon's two-stage\*  
Stage 1 N=17, stop if 5 or fewer responses.

Assessment period = up to 18 months

## Primary Endpoint

- Tumor ablation rate

## Secondary Endpoints

- AEs & SAE's - safety and tolerability
- Local recurrence rate
- Progression Free Survival (RECIST v1.1)

## Exploratory

- General Cancer QoL (EORTC QLQ-C30)
- Head and Neck QoL (EORTC QLQ-H&N35)
- Tumor response in injected and non-injected tumors
- Assessment by itRECIST
- Wound Healing
- ORR (RECIST v1.1 and itRECIST)
- Immune infiltration in surgical/biopsy specimens
- ctDNA ; PBMC's

## Top Line data

- Interim data Q2 2024
- Full data Q2 2025

TT, tigilanol tiglate; AE, adverse event; SAE, severe adverse event; CPI, checkpoint inhibitor; CT, computed tomography; ECOG, Eastern cooperative oncology group; MRI, magnetic resonance imaging; Q4W = every 4 weeks; Tx1, Tx2- Tx5 = tigilanol tiglate treatment of the same tumour, BSA = Body Surface Area, ORR = Overall Response Rate; QoL = Quality of Life; EORTC = European Organisation for Research and Treatment of Cancer.  
\*The null hypothesis will be rejected if 14 or more responses are observed in 37 participants. This design yields a type I error rate of 0.05 and power of 90% when the true response rate is 50%.



# An Exploratory Phase II, single-centre, open-label study (QB46C-H07) assessing the preliminary efficacy of tigilanol tiglate in patients with advanced and/or metastatic soft tissue sarcoma (NCT05755113)

There are

**80** different types of soft tissue sarcoma

~124 573 new cases each year<sup>1</sup>



## Unmet need

Safe and effective treatments, especially for advanced disease



Total Market Value **\$US 1.2 billion** (by 2023)<sup>2</sup>



## Patient Population

- Adults with advanced and/or metastatic soft tissue sarcoma
- $\geq 1$  measurable lesion by ultrasound ( $\pm$ CT or MRI) accessible for intratumoral injection (cutaneous, subcutaneous)
- ECOG PS  $\leq 2$
- Allow surgical candidates
- Allow CPI-experienced and prior systemic treatments and radiotherapy

## Tx1 Phase

Tigilanol tiglate intralesional ( $\leq 3.6$  mg/m<sup>2</sup> BSA)

## Additional Treatments Tx2 to Tx5

Residual Tx1 Tumor

OR

Additional tumors

Surgery

OR

Up to total of 5 repeat injections of TT to be given Q4W per tumor

Determination of tumour ablation rate

Total n=10 patients  
Assessment period = 6 months

## Primary Endpoint

- Tumor ablation rate at 28 days

## Secondary Endpoint

- AEs & SAE's - safety and tolerability
- Pharmacokinetics

## Exploratory

- Immune infiltration in surgical/biopsy specimens
- PBMC's
- Local recurrence rate (up to 6 months)

## Top Line data

- Interim data Q1 2024
- Full data Q3 2024

TT, tigilanol tiglate; AE, adverse event; SAE, severe adverse event; CPI, checkpoint inhibitor; CT, computed tomography; ECOG, Eastern cooperative oncology group; MRI, magnetic resonance imaging; Q4W = every 4 weeks; Tx1, Tx2, Tx3 = tigilanol tiglate treatment of the same tumour, BSA = Body Surface Area



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### Anti-inflammatory



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- **Phase II** trial in patients with soft tissue sarcoma (QB46C-H07)
- Parallel translational research program



## Organisation

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- **Seeking partners to accelerate development & commercialization**



Thank you



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Harnessing the power of  
nature to improve lives.

E: [Richard.Godfrey@qbiotics.com](mailto:Richard.Godfrey@qbiotics.com)

[qbiotics.com](http://qbiotics.com)