QBiotics Group

Harnessing the power of nature to improve lives

BIO International - June 2023

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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

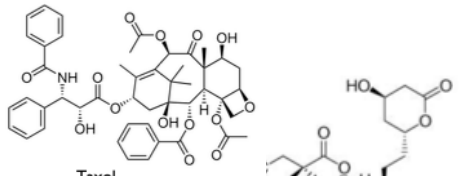
Organisation

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

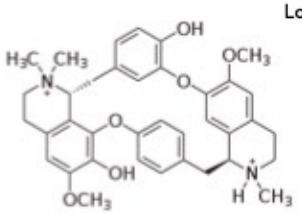
EcoLogic™
Translating ecological knowledge into novel therapeutics

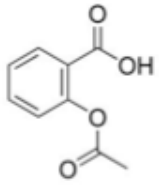
Why go back to nature as a source of new drug scaffolds?

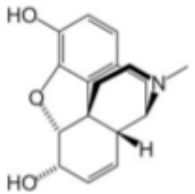
Produced in nature = demonstrated compatibility with the cellular environment


Taxol

Lovastatin


Tubocurarine

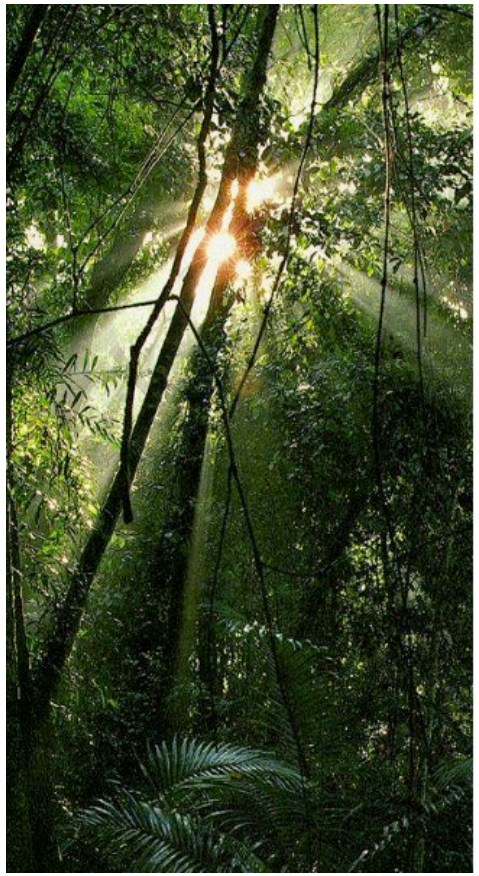

Aspirin


Morphine

- 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

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

Human

Therapeutic Area	Lead Molecule	Trial ID	Indication	Stage of Development: Pre-clinical / Phase I / Phase II / Phase III / Registration / Marketing
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

Therapeutic Area	Lead Molecule	Species & Indication	Clinical / Registration / marketing
Oncology	Tigilanol tiglate	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 anenestic 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

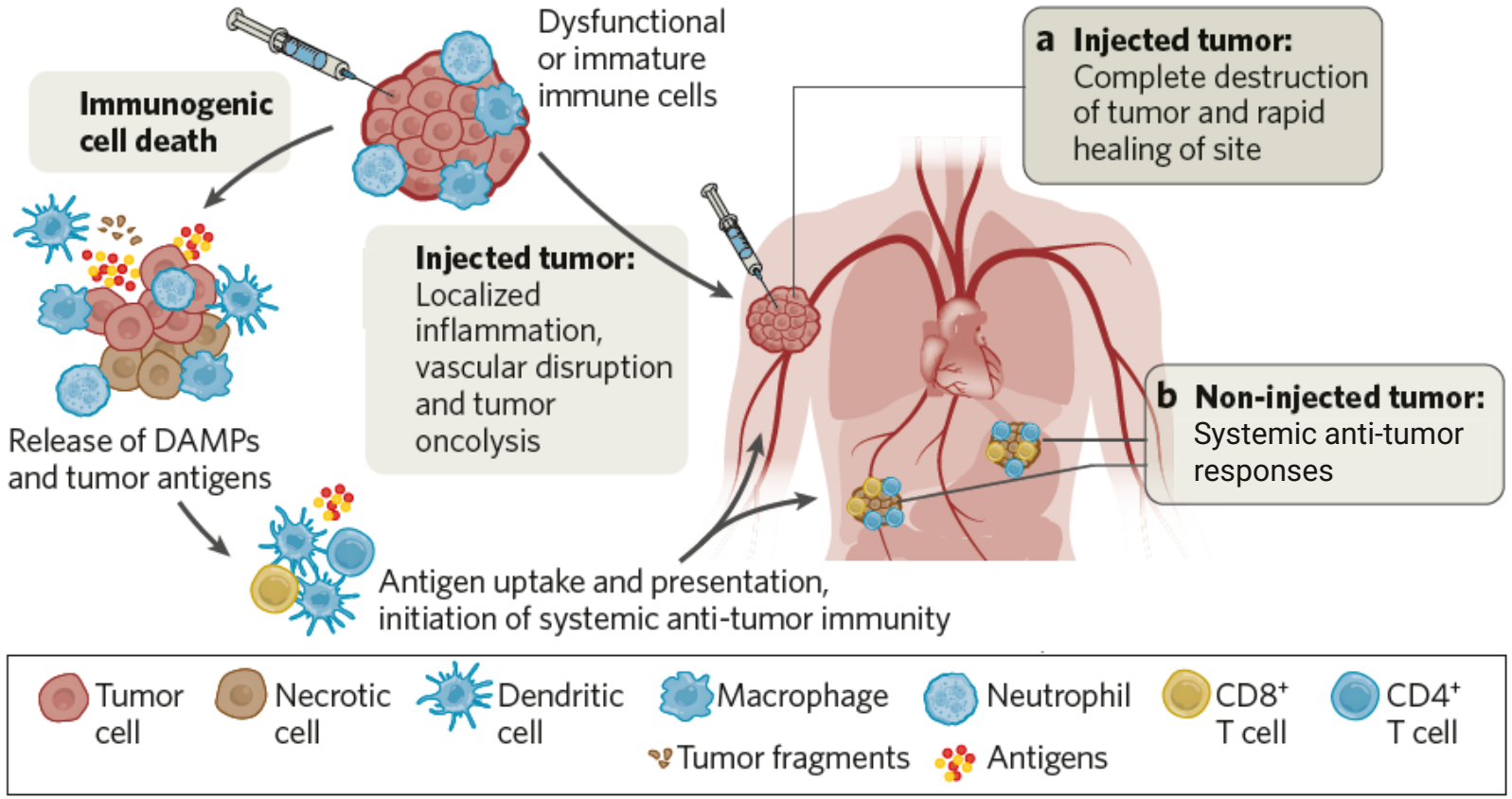
Very effective & well tolerated 'pan-tumor' small molecule Potential for development in multiple cancers:

- 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 | March 2022

Boyle *et al*. (2014). PLoS ONE. Cullen *et al*. (2021). Scientific Reports

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^2 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

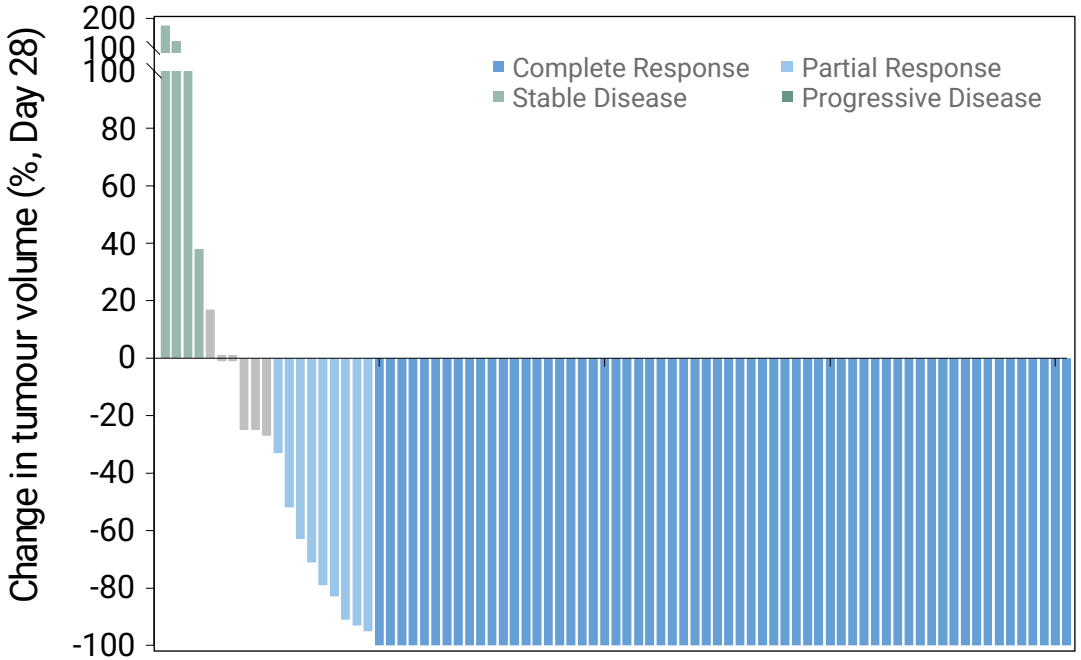
The Kinghorn Cancer Centre
The ROYAL MARSDEN NHS Foundation Trust
Memorial Sloan Kettering Cancer Center
NHS Guy's and St Thomas' NHS Foundation Trust
The Kinghorn Cancer Centre
GIG CYMRU NHS WALES

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



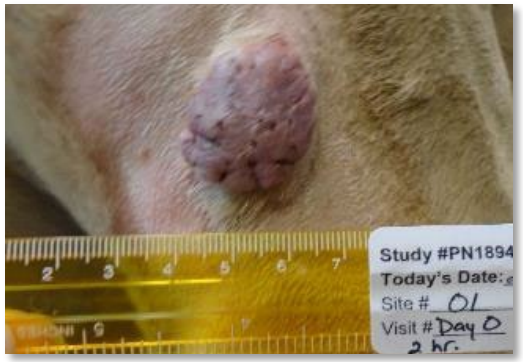
Tumor response in tigilanol tiglate treated dogs (n=81)

✓*75% CR with a single IT treatment (p<0.0001 vs sham control)*[1]

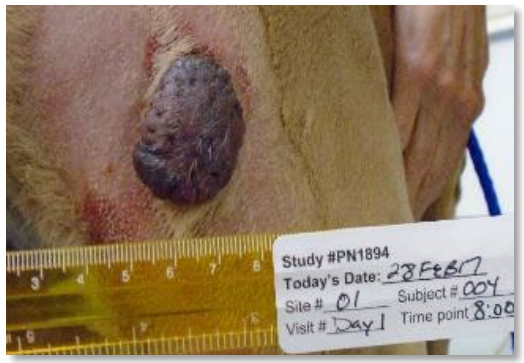
✓***Objective Tumor Response Rate (CR/PR) of 80%***

✓*88% CR with a second treatment for partial responders. No tumor recurrence in 89% of evaluable cases (n=57) at 12 months*[2]

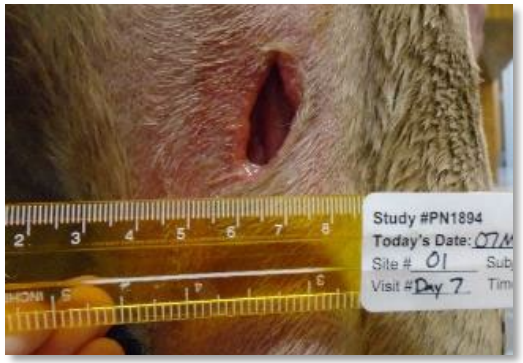
Clinical case from US FDA-CVM registration trial



Day 0: Pretreatment



Day 1: tumor haemorrhagic necrosis



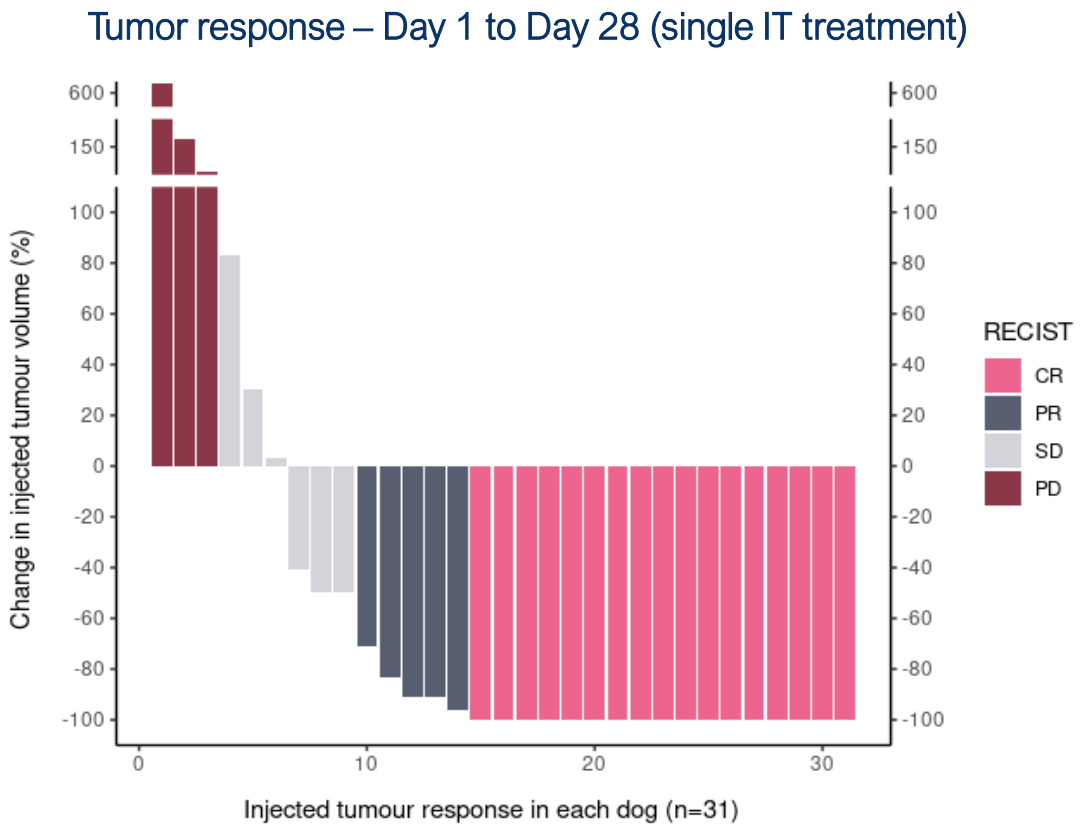
Day 7: tumor destroyed (CR)

Day 28: Site healed

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)*[1]
- ✓***Objective Tumor Response Rate (CR/PR) of 61.9%***[2]
- ✓*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[2].*

Canine Case Study

Single treatment Led to a Complete Response in Recurrent STS

Case ID: 35-001
7 yr, 9 mo Beagle

Histogenesis:

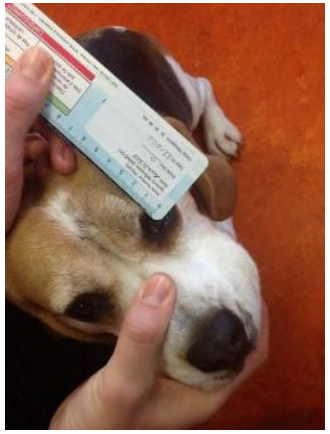
Grade 1 Soft tissue sarcoma that had recurred following surgery eight months prior

Treatment:

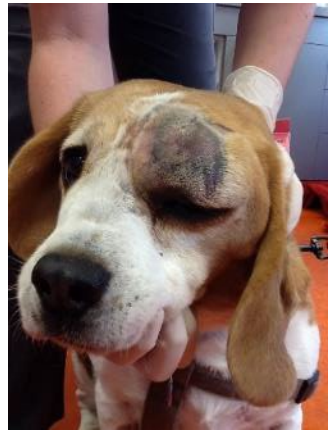
Tumour Vol: 3,600 mm^3
Single IT injection

Result:

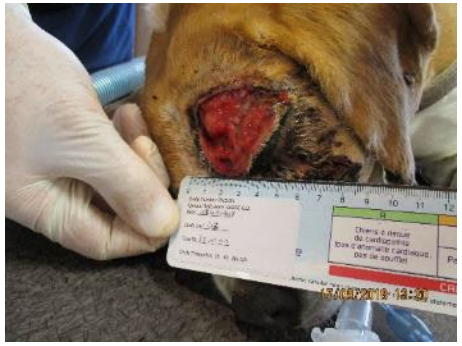
Complete Response



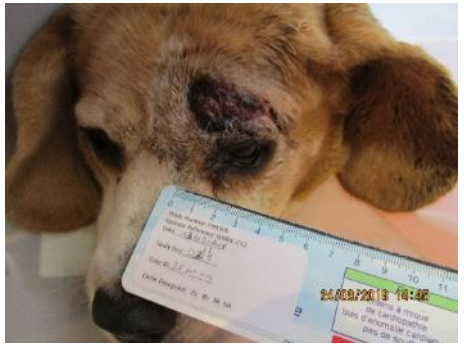
Pre: Soft tissue sarcoma above left eye



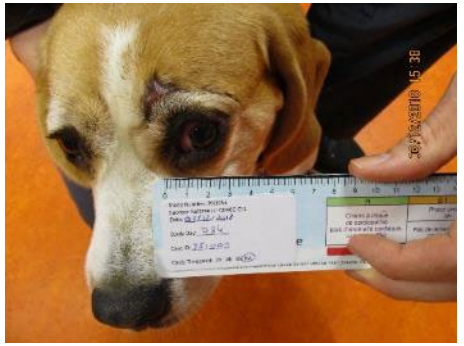
Day 1: Swelling and necrosis



Day 7: Tumor destroyed



Day 14: Wound healing



Day 84: No recurrence

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Canine Case Study

Single treatment Led to a Complete Response in Oral Melanoma

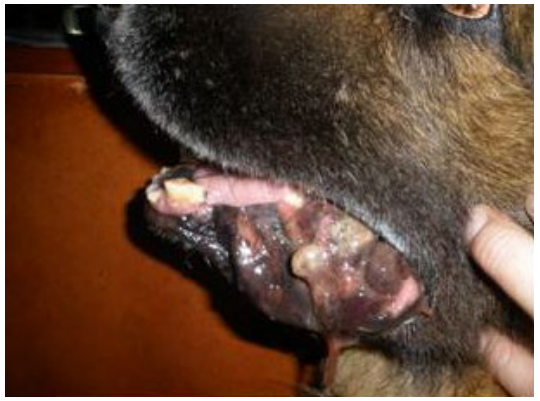
12 yo German Shepherd

Histogenesis:
Oral melanoma

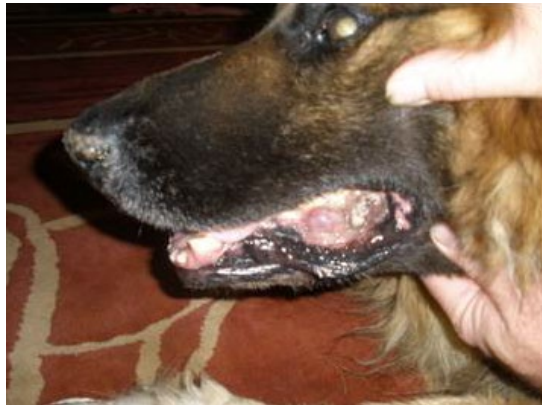
Treatment:
Single IT injection

Result:
Complete Response

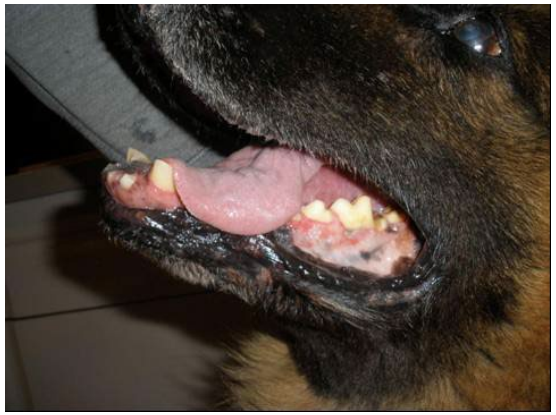
Pretreatment



Day 4: Tumor necrosis evident



Day 17: Tumor necrosis almost complete, wound healing well advanced



Day 210: Site completely healed* no tumor regrowth

* Day 210 was when owner returned dog to vet; site healed well before this

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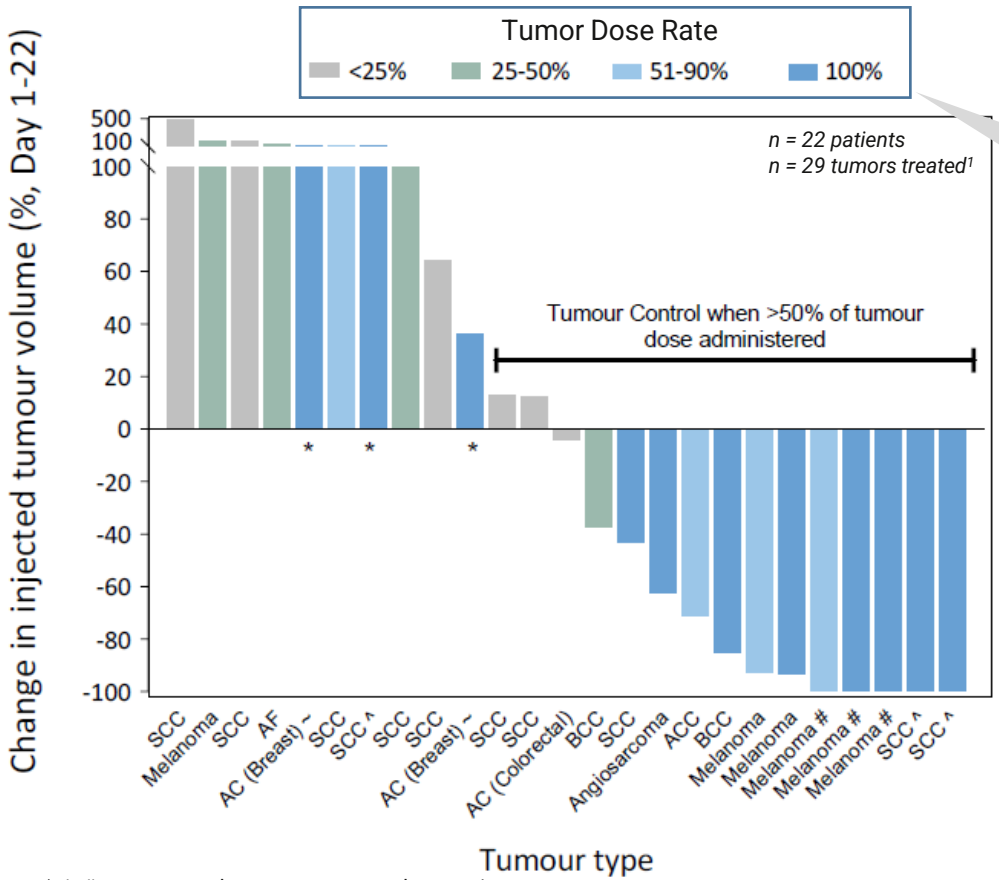
Phase I (QB46C-H01)

Tigilanol tiglate has shown remarkable clinically relevant responses with a single injection

Tigilanol tiglate monotherapy

Tumor response of single IT treatment at **escalating doses**



^, *, #, ~ = two or three tumors treated per patient

• = highly ulcerated tumor and leakage of tigilanol tiglate, so full treatment rate not administered

- **Tigilanol tiglate well tolerated**; AEs mild and transitory
- Clinically relevant tumor responses in all **nine tumor types**
- **20 of 22 patients** had a response to treatment
  4 CR[2], 3 PR, 13 SD
- **2 patients had non-injected** tumor (anenestic) responses[3]
- Best responses when tumors receive optimal dose rate

	Phase I
	Optimal Dose Rate 100% tumor dose (n = 6 pts)[4]
Complete Response (CR)	50% (3/6)
Local Tumor Control (CR/PR/SD)	100% (6/6)

Tumor control reported in Squamous Cell Carcinoma (SCC), Melanoma (BRAF), Basal Cell Carcinoma, Angiosarcoma, Atypical Fibroxanthoma (AF), Fibrosarcoma, Breast and Colorectal Adenocarcinoma (AC), and Adenoid Cystic Carcinoma (ACC)

[1] *Four tumors not assessable.*

[2] *Two patients reported CR's post-study by Panizza et al., 2019. EBioMedicine*

[3] *Panizza et al., 2019. EBioMedicine*

[4] *Best RECIST response of injected tumor by calipers from Day 1.*

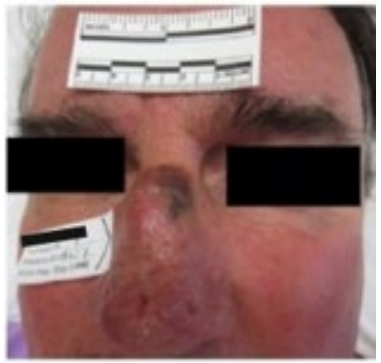
Soft Tissue Sarcoma:

Complete response with a single injection of tigilanol tiglate[1]

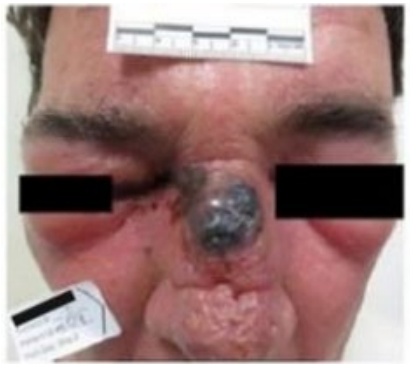
- Patient had failed surgery
- Difficult to treat lesion, patient initially advised a total rhinectomy

Pt 407 - Soft Tissue Sarcoma (Angiosarcoma)

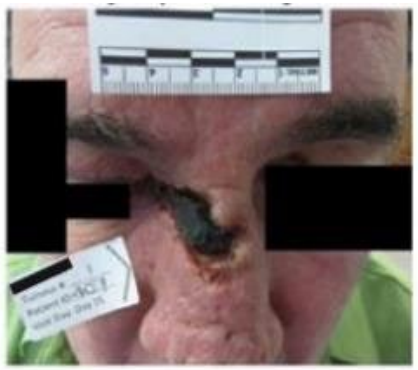
- Tumor size: 5,141 mm^3
- Single IT treatment at optimal dose rate



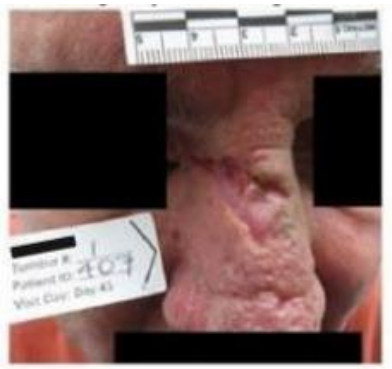
Pretreatment



Day 2: vascular disruption and haemorrhagic necrosis of tumors



Day 15: tumor necrosis continues



Day 43: Complete Response2

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

[1]*Phase I Clinical Study Report QB46C-H01 and Panizza et al., 2019. EBioMedicine*
[2]*Reported off study by Panizza et al., 2019. EBioMedicine*

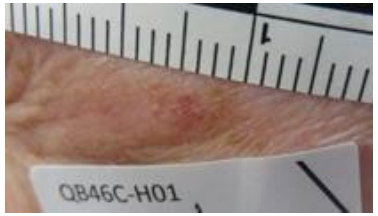
Squamous Cell Carcinoma:

Complete response with a single injection of tigilanol tiglate[1]

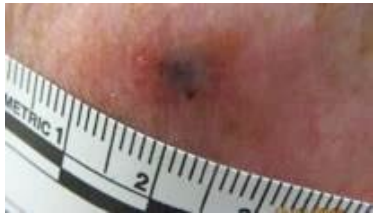
- Patient had failed earlier radiotherapy and chemotherapy treatments[1]

Pt 202 - Squamous Cell Carcinoma on cheek

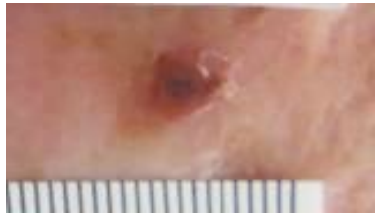
- Tumor : 200 mm^3
- Single IT treatment at optimal dose rate



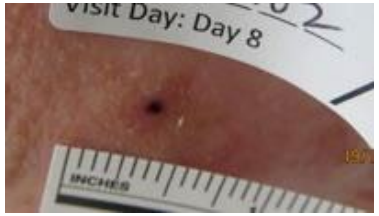
Pretreatment



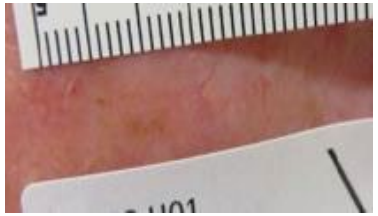
Day 1: Vascular disruption and haemorrhagic necrosis of tumors



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*

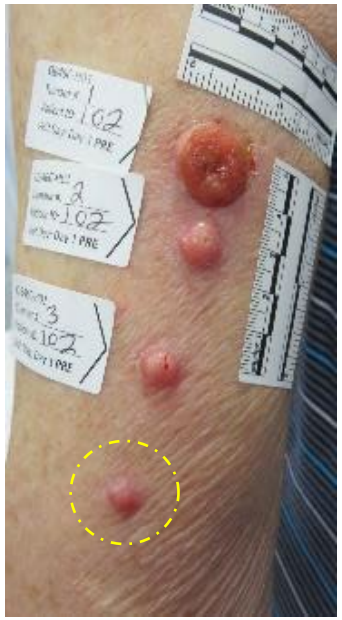
[1]Patient had received prior treatment with radiotherapy, cetuximab, cisplatin and 5FU (> 7 months prior to treatment with tigilanol tiglate)

Metastatic melanoma

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

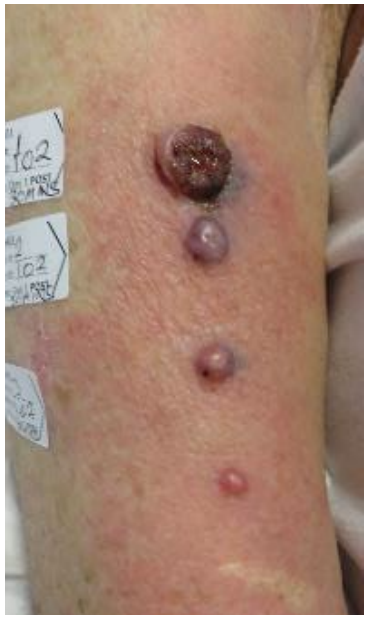
Pt 102 - Multiple melanoma

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



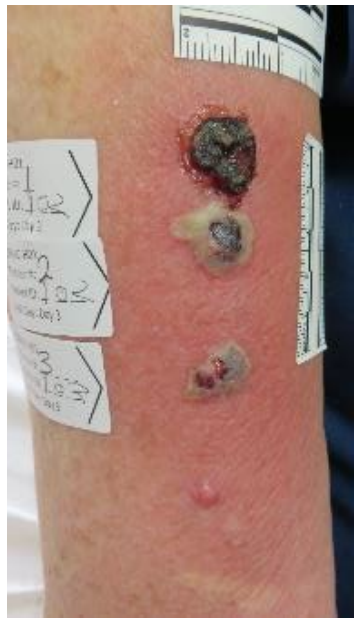
Day 1: Pretreatment

4 tumors on upper arm

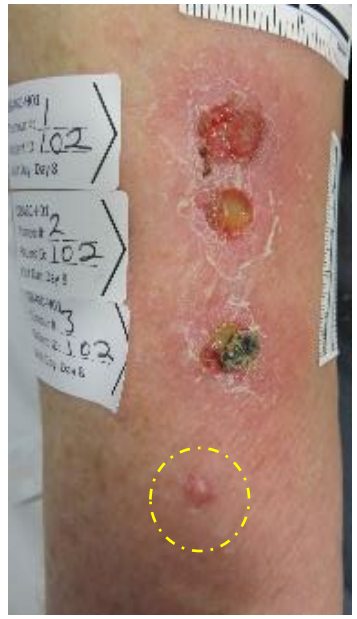


Day 1: 30 minutes post:

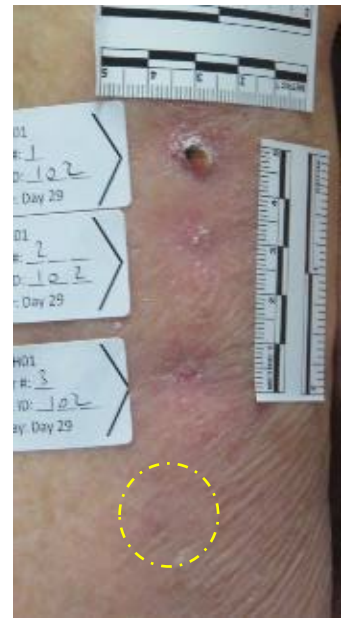
Vascular disruption and hemorrhagic necrosis of tumors



Day 3: Necrotic tumors slough



Day 8: Non-injected, 4th tumor (circled) regresses



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

Lung & sternum tumor regressed - reported off study[1*]

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

7TH most common cancer worldwide

~932,000 new cases each year[1]

Unmet need

Unresectable
Locally advanced
Recurrent/Metastatic disease

Total Market Value **$US 5.2 billion** by 2030)[2]

>108,000 patients unresectable head and neck tumors

Patient Population

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

Tx1 Phase

Tigilanol tiglate intralesional (≤3.6 mg/m² 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%.*

1. Globocan, 2020. 2. GlobalData

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[1]

Unmet need
Safe and effective treatments, especially for advanced disease

Total Market Value
$US 1.2 billion
(by 2023)[2]

Patient Population

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

Tx1 Phase

Tigilanol tiglate intralesional (≤3.6 mg/m² 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

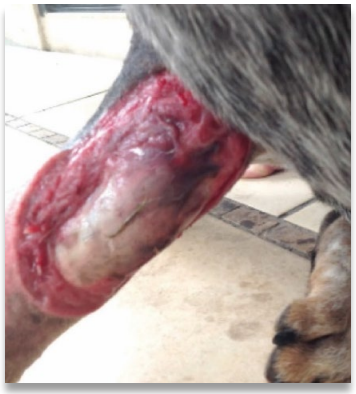
- Interim data Q1 2024
- Full data Q3 2024

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

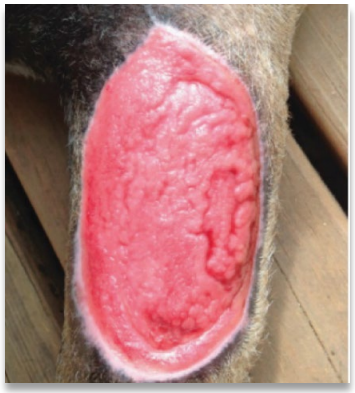
1. Global Data 2. Grandview Research

EBC-1013: Wound healing - veterinary case studies

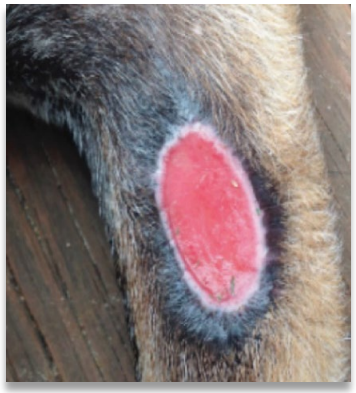
Canine surgical wound, closure not possible (3 treatments, 7 days apart)



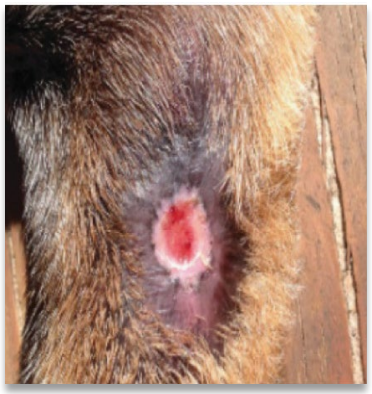
Pre-treatment



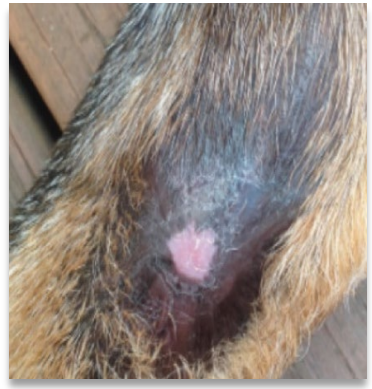
Day 19: Wound in-fill



Day 42



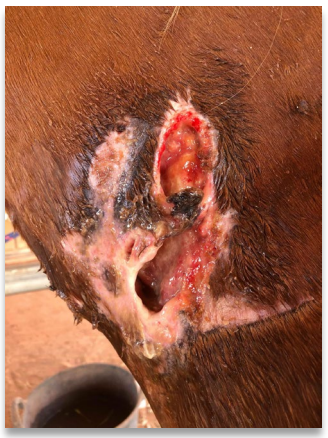
Day 63



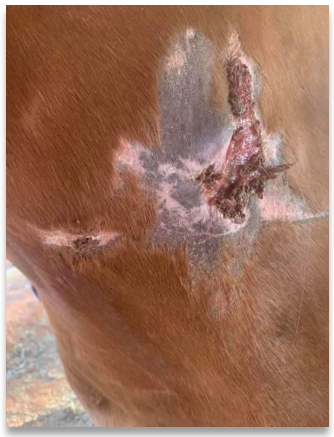
Day 78

Equine traumatic penetrating wound (1 gel application)

Day of wounding

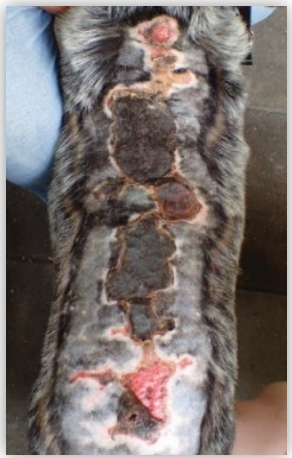


Day 0 (infected wound 5 days after trauma)

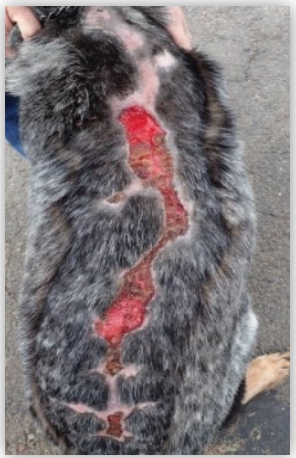


5 day after treatment

Canine thermal burn (3 treatments, 7days apart)



Treatment Day 1
(8 days after burn)



Day 14

Day 38

Day 73

QBiotics Group

Clinical Development Key milestones

Human

Oncology
Soft tissue sarcoma
Head & Neck

Wounds
Venous leg ulcers

Tigilanol tiglate
Phase II STS
First patient

Tigilanol tiglate
Phase II H&N
First patient

EBC-1013
Ph I/II VLU
First patient

Tigilanol tiglate
Phase II STS
Interim data

EBC-1013
Ph I/II VLU
Interim data

Tigilanol tiglate
Phase II H&N
Interim data

Tigilanol tiglate
Phase II STS
Final report

EBC-1013
Ph I/II VLU
Final report

Tigilanol tiglate
Phase II H&N
Final report

Q1 Q2 Q3 Q4 2023 | Q1 Q2 Q3 Q4 2024 | Q1 Q2 Q3 Q4 2025

Veterinary

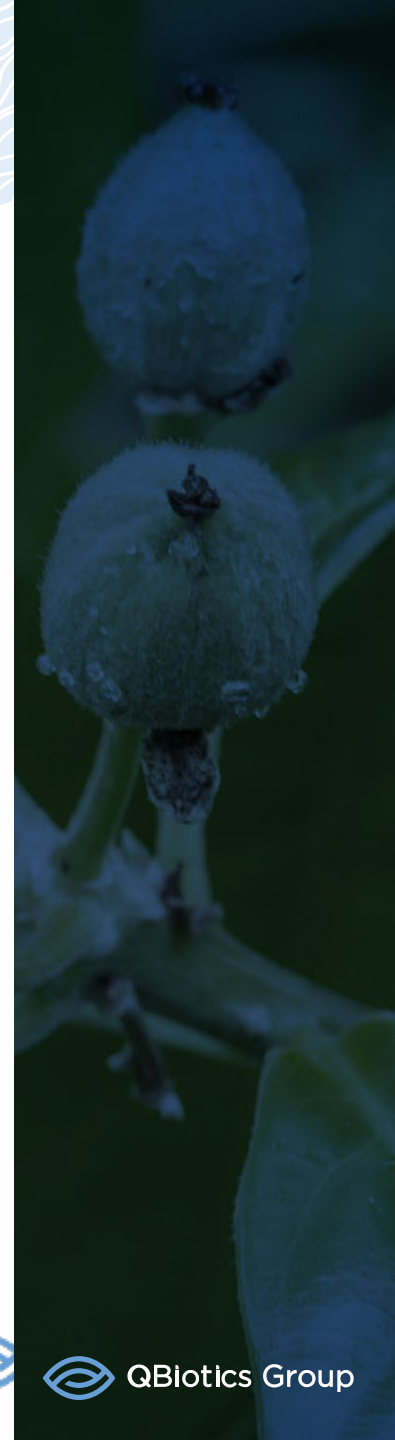
Oncology
Equine sarcoids & melanoma
Canine soft tissue sarcoma & oral melanoma

STELFONTA® (tigilanol tiglate)
Phase IV equine sarcoids
Final report

STELFONTA® (tigilanol tiglate)
Phase IV equine melanoma
Final report

STELFONTA® (tigilanol tiglate)
Phase IV canine STS
Final report

STELFONTA® (tigilanol tiglate)
Phase IV canine oral melanoma
Final report



QBiotics Group

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

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**

Thank you

QBiotics Group

Harnessing the power of nature to improve lives.

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qbiotics.com