



Bioshares Biotech Summit

13 July 2024

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General Counsel



QBiotics Group

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QBiotics Group company overview



Australian unlisted life sciences company

Specialists in plant-derived, cell signalling small molecules

Founded Discovery Co. 2000; Development Co. 2010



EcoLogic™ unique discovery platform



Sound scientific expertise

Team of 57 employees

6 PhD, 1 MD, 1 DVM (oncology) 5 BVSc, 9 BSc



Global contracts

- Clinical Advisory Board
- 7 Universities
- 2 Research Institutes
- 49 CRO/CMO providers and advisors



Focus oncology and wound healing

Oncology - solid tumours clinical Phase II

- Soft tissue sarcoma
- Head and neck cancer

Wound healing – chronic/acute, burns clinical Phase I

- Venous leg ulcers

Discovery programs in antibiotics and anti-inflammatories



Veterinary data underpins human programs

Informs and derisks early-stage human clinical

- STELFONTA registered for canine MCT
- Approved FDA-CVM, EMA, VMD, APVMA
- Marketed by 



Sound IP coverage

Composition of matter and use patents on all products

QBiotech Overview

As at 30 June 2024 (AUD)



\$439M

Market capitalisation
- at last capital raise at
\$0.90 per share (June
2021)



\$194M

Capital raised to date



\$60.3M

R&D tax incentive
refunds and Gov.
grants received to date



\$4.2M

Quarterly burn rate**



\$43.3M

Current cash at bank*

*30 June 2024 **1 April to 30 June 2024

Ecologic™: ecological approach to biodiscovery

Novel, biologically active small molecules for human & animal health

EcoLogic®

90%

Biodiscovery
success



Understand the ecosystem



Discover bioactive molecules



Combine

Plant ecological attributes



Distribution-
environmental
niches



Phenology



Stress & disease
responses

With

Plant-animal interactions



Dispersal



Pollination



Herbivory



[Play : QBiotics EcoLogic™ video](#) 

Product pipeline

Molecule

Tigilanol tiglate

EBC-1013

Leads

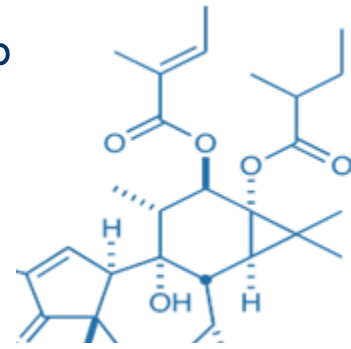
Stage of Development

Therapeutic Area	Disease	Discovery	Preclinical	Phase I	Phase II	Phase III	Regn. Marketing	Partner
Oncology (Human)	Head & Neck Cancers	-	Phase II recruiting					
	Soft Tissue Sarcoma (STS)		Phase II recruitment complete					
Oncology (Veterinary)	Canine: Mast Cell Tumours		Stelfonta® - Marketed EU, USA, UK and Australia					
	Canine: STS & Oral Melanoma		Recruiting					
	Equine: Sarcoids & Melanoma		Sarcoids reporting; Melanoma recruiting					
Wound healing (Human)	Venous Leg Ulcers		Phase I recruiting					
Wound healing (Vet')	Chronic wounds & burns		Veterinary models - ongoing					
Next Gen' Antibiotics	Multi Resistant Organisms		Leads developing					
			Leads developing					
Anti-inflammatory/ Neuroprotectants	Arthritis, Alzheimer's		Leads developing					

Tigilanol Tiglate Oncology

QBiotech Group

Tigilanol tiglate novel epoxytigliane overview



Unique and differentiated MoA

- Pan tumour
- In most cases, single IT injection
- Rapid tumour destruction
- Site healing
- Systemic anti-tumour immune response



Clinical Phase I trials sound data

- Well tolerated
- MTD not reached
- Activity in nine tumour types
- ICD markers and CD8+ T cell infiltration in human HNSCC tumour biopsies



Two Phase II trials current

- Soft tissue sarcoma
 - MSKCC USA
 - Patient recruitment finalised
 - FDA Orphan Drug Designation
- Head and neck cancers
 - Royal Marsden
 - 5 sites UK, 2 sites AU



Regulatory and Commercial validation in veterinary market

- STELFONTA®
- Canine MCT
- USA, UK, EU & AU



Commercial Qualities

- Commercial manufacturing & supply
- Comparative low COG
- Simple to use
- Good stability drug product
 - 4+ years 2-8°C
 - 12 months RT
- Sound patenting profile



Significant Growth Opportunities

- Multiple tumour indications
- External and internally located
- Late and early settings
- Strong monotherapy activity
- Combination potential ICI, chemotherapy, radiotherapy

STELFONTA[®] (tigilanol tiglate)

Commercialised across key markets



- Proven veterinary pharmaceutical for treatment of canine mast cell tumours
- >20,000 dogs treated to date
- Global supply chain, marketing and distribution network with partner Virbac
- Regulatory, CMC and commercial validation
- In development for other species & tumour types
- Disruptive technology – First line alternative to surgery for surgical GPs and veterinary oncologists

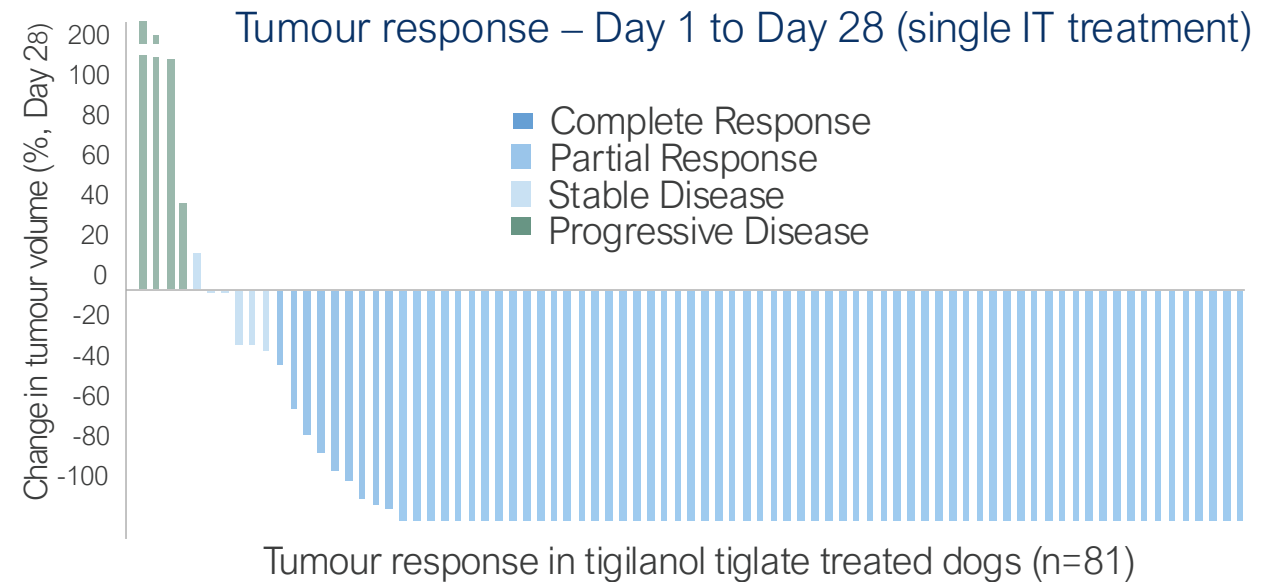


Canine US FDA-CVM Registration trial

Single treatment induces Complete Responses in 75% canine mast cell tumours



- GCP, randomized, blinded, sham controlled study; eleven sites
- 123 Dogs: 81 treated with tigilanol tiglate vs 38 sham control
- 75% CR with a single IT treatment ($p < 0.0001$ vs sham control)¹
- Objective Tumour Response Rate (CR/PR) of 80%
- 88% CR with a second treatment for partial responders
- No tumour recurrence in 89% of evaluable cases ($n=57$) at 12 months²



Progression of clinical response in canine case from US FDA-CVM registration trial



Day 0: Pre-treatment



Day 1: Tumour haemorrhagic necrosis



Day 7: Tumour destroyed (CR)



Day 28: Site healed

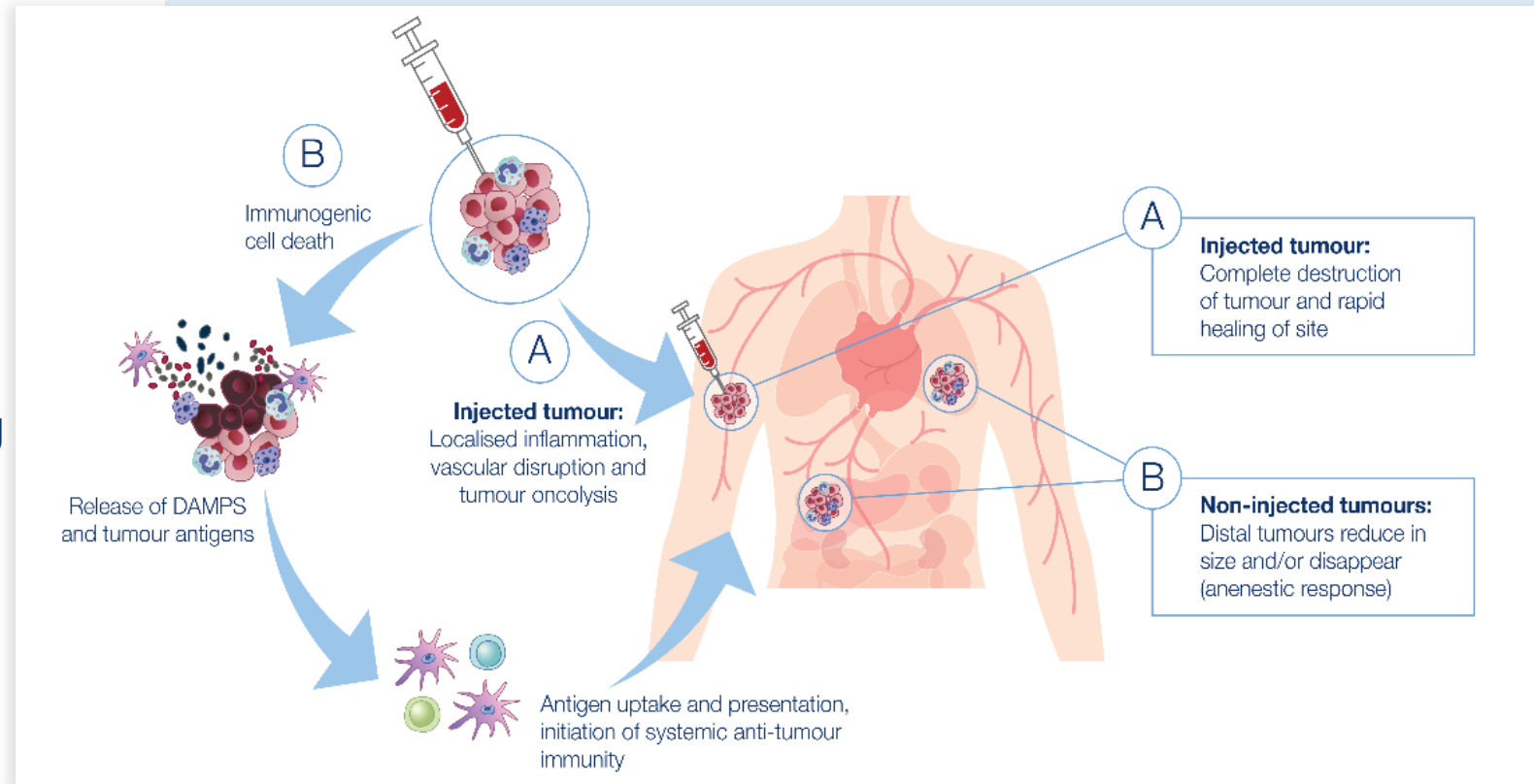
¹QBiotics Study Report PN1894. RECIST v1.1 applied to injected tumour. Published by [De Ridder T. et al \(2020\)](#). ² [Jones et al., 2021](#)

Tigilanol tiglate mode of action



Tigilanol tiglate is a Protein Kinase C activator

- A. Induces rapid tumour destruction in injected tumours within 5-7 days and induces good healing of site
- B. Non-injected tumours regress by immune-mediated mechanisms



DAMPS = Damage Associated Molecular Patterns



Phase I - QB46C-H01

Open label, multicentre, single arm dose escalation (3+3) of single intratumoural injection with tigilanol tiglate¹



Patient population:

- Advanced refractory skin & subcutaneous tumours
- 22 patients



Dose:

- 0.06, 0.12, 0.24, 0.60, 1.2, 2.4, 3.6 mg/m² body surface area (BSA)



Good safety profile:

- No serious AEs
- MTD not reached



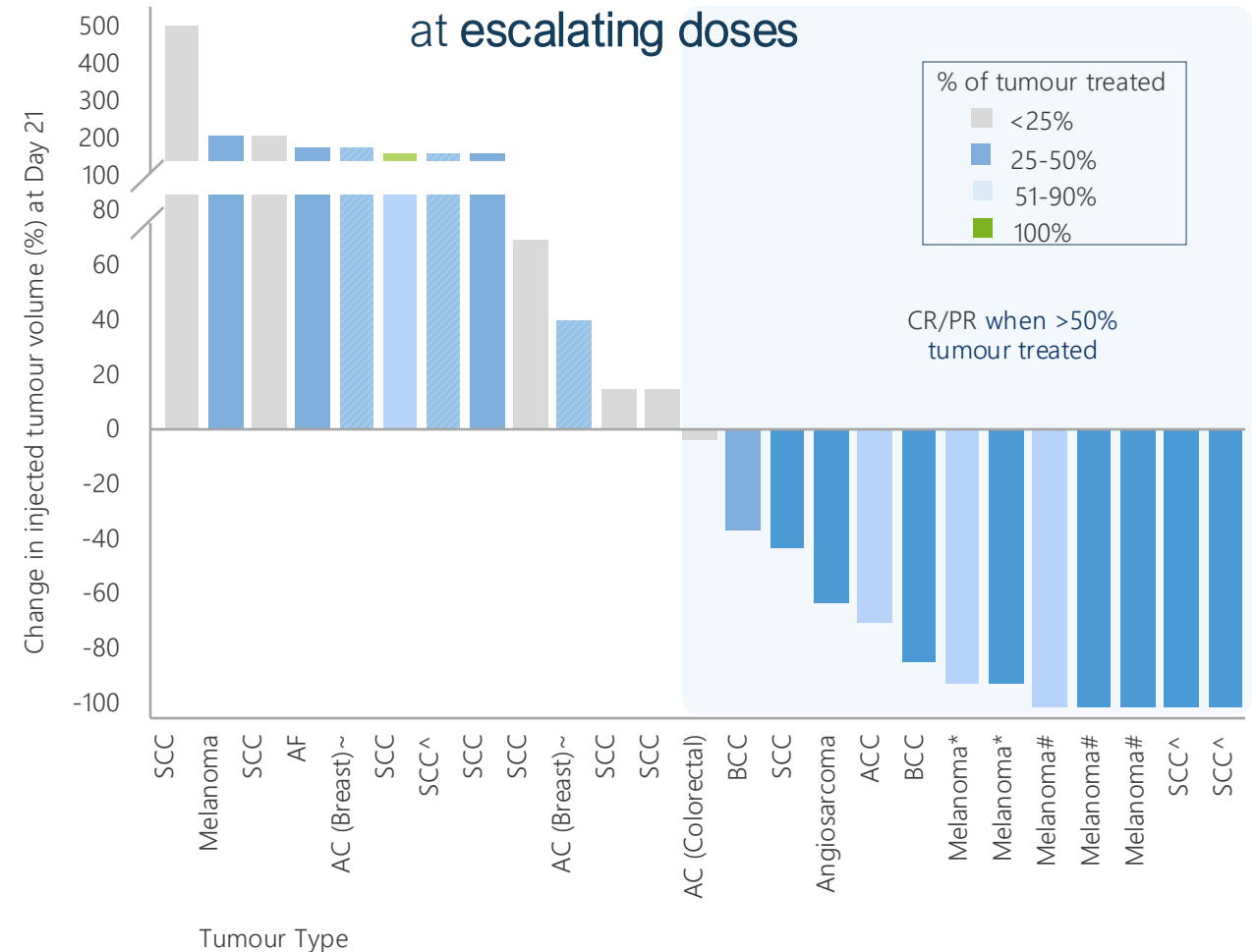
Signs of efficacy in all 9 tumour types treated:

- Complete Response when 100% tumour treated

^, #, ~ = two or three tumours treated per patient

*= highly ulcerated tumour and leakage of tigilanol tiglate, so full treatment rate not administered
Squamous Cell Carcinoma (SCC), Melanoma (BRAF), Basal Cell Carcinoma, Angiosarcoma, Atypical Fibroxanthoma (AF), Fibrosarcoma, Breast and Colorectal Adenocarcinoma (AC), and Adenoid Cystic Carcinoma (ACC)

Tumour response of single IT treatment at escalating doses



¹Panizza et al., 2019. *EBioMedicine*. QBiotics Study QB46C-H01.

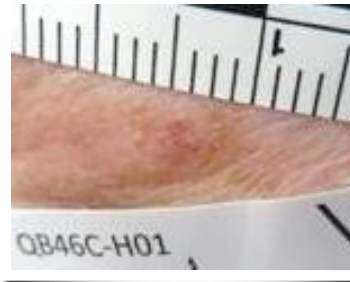
Phase I- Case Study Squamous Cell Carcinoma

Complete response with a single injection of tigilanol tiglate

Patient had failed earlier radiotherapy and chemotherapy treatments¹

Pt 202 - Squamous Cell Carcinoma on cheek

Single IT
treatment (100%
tumour treated)



Pre-treatment



Day 1: Vascular
disruption and
haemorrhagic
necrosis tumour



Day 5: Tumour
necrosis continues



Day 8: Tumour
necrosis continues



Day 15: Complete
Response



Complete Response at Day 15, with no scarring



Tigilanol tiglate well tolerated; AEs mild and transitory

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

¹Panizza et al., 2019. EBioMedicine. QBiotics Study QB46C-H01.

Example cases QB46C-H01/2

Patient 102: Metastatic melanoma



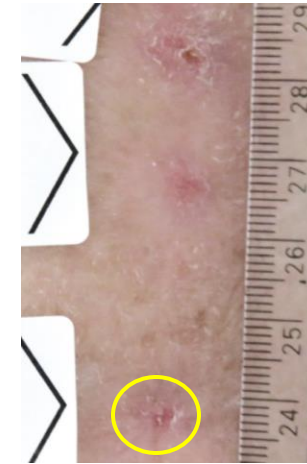
Pre-treatment



Day 1: 30 mins:
tumour necrosis



Day 8: Non-injected,
4th tumour regresses



Day 35: CR in the non-
injected tumour

Single IT injection

- Into top 3 tumours - 4th tumour (circled) not treated
- Abscopal response in lung & sternum tumours reported off study as an abscopal effect

Patient 404: Metastatic melanoma – failed ICI and multiple surgeries



Pre-treatment



Day 2: Tumour necrosis



Day 29: Complete Response



24 months: Patient
tumour free

Single IT injection into 2 tumours in axilla

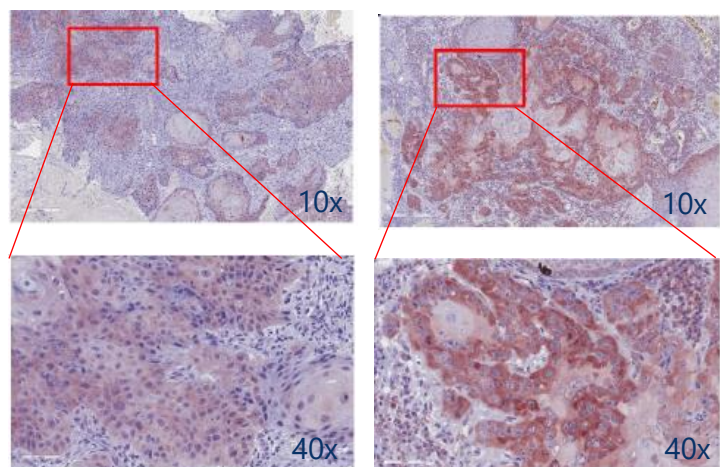
Abscopal response in:

- Nodal deposit and leg melanoma - both cleared
- Patient clinically and ultrasound clear at 33 months post-treatment

QB46C-H03 Phase I/IIa HNSCC window of opportunity before surgery

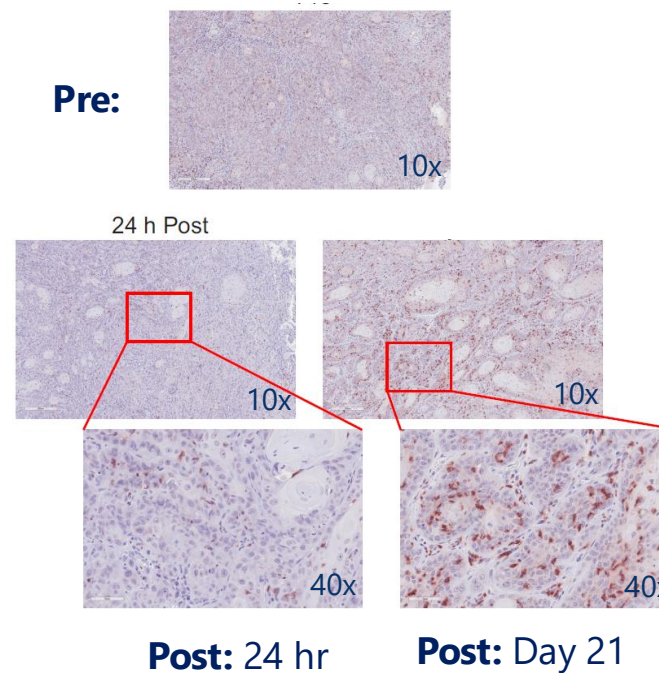
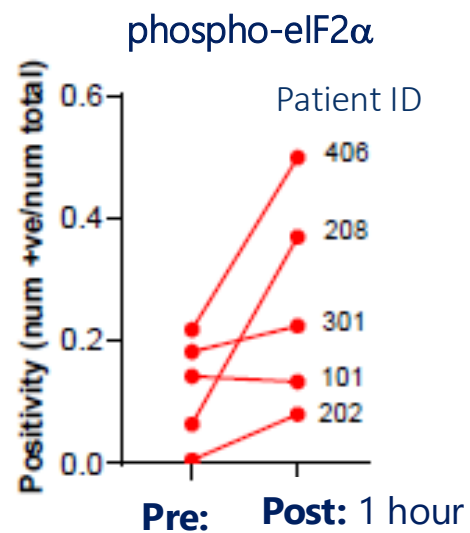
ICD indication and T cell infiltration in treated human tumours

Patient 208



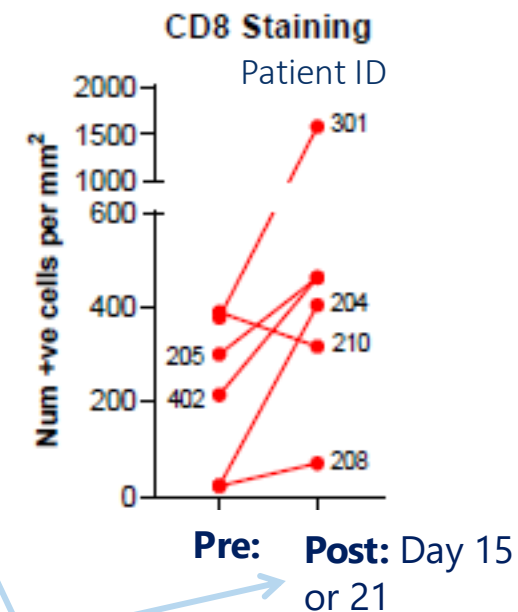
Pretreatment

Post: 1 hour



Post: 24 hr

Post: Day 21



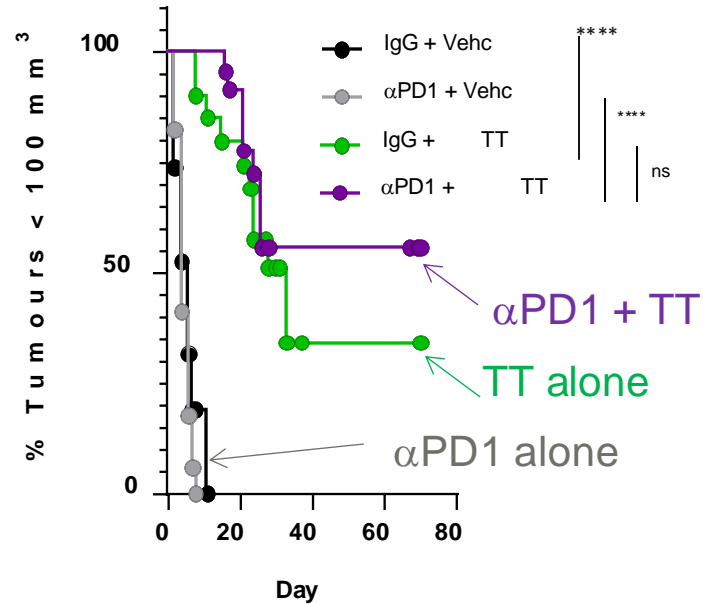
Increased phosphorylation of eIF2α (pathognomonic marker of ICD) in HNSCC biopsies 1 hour post treatment

Increased CD8+ T cell infiltration in HNSCC tumours surgically excised at Day 15 or 21

TT = tigilanol tiglate

Significantly improves survival in mouse studies, when combined with ICI, chemotherapy and radiotherapy

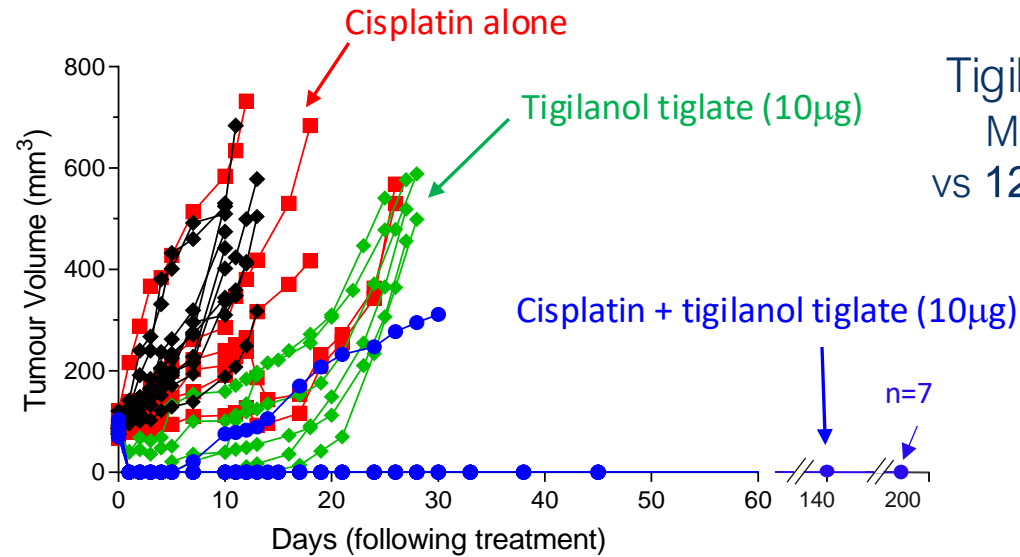
Tigilanol tiglate + α PD-1
increases survival and regresses tumours in ICI refractory melanoma



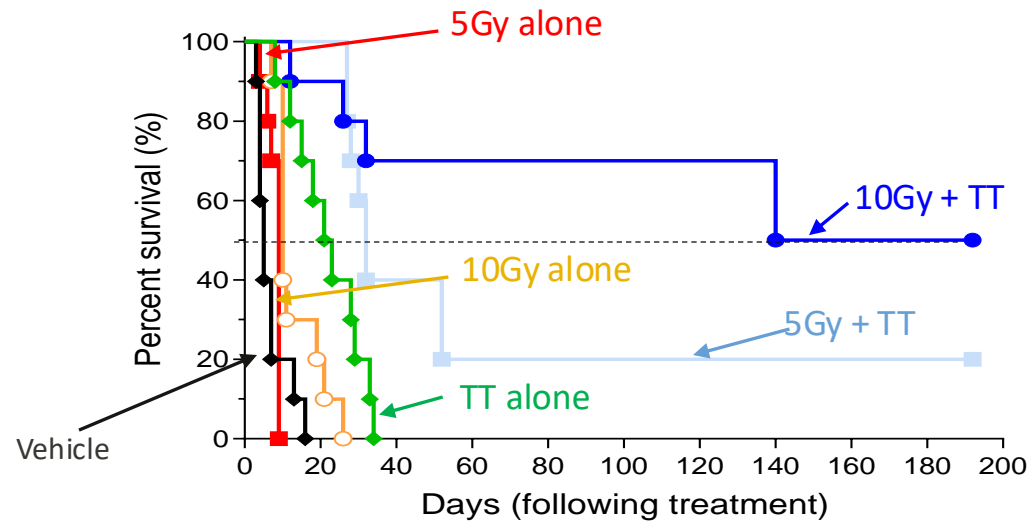
N=10 animals per group. **** $p < 0.0001$;
Log rank (Mantel-Cox) test

**** $p < 0.000001$; **** $p < 0.00001$; ** $p < 0.001$.

TT = tigilanol tiglate



Tigilanol tiglate + Cisplatin
Median survival **193 days**
vs **12 days** with Cisplatin alone



Tigilanol tiglate +
radiotherapy
Median survival **166 days**
vs **10 days** with
radiotherapy alone

HNSCC market & tigilanol tiglate potential

Potential for tigilanol tiglate as monotherapy - preservation of organ function & good cosmetic outcome
 Potential for tigilanol tiglate in combination with standard of care – improved efficacy and safety

Incidence and unmet need



- Head and neck squamous cell carcinoma (HNSCC) is the 7th most common cancer globally ~ 890,000 new cases in 2023¹ – OS remains a major unmet need
- Standard of Care is surgery and chemoradiation, +/- EGFR inhibitors (Erbix, Eli Lilly) and CPIs (Keytruda, Merck) in later settings
- Surgery is complex due the need to preserve vital organ function

Market Size



- HNSCC market ~\$US2.1B in 2020²
- CAGR of 9.8% sales of \$5.2 B by 2030²

Opportunity



- No intratumoural product is approved
- Fewer products in development for HNSCC than other cancers
- Opportunity to preserve organ function & improved cosmetic outcomes
- Combination with Standard of Care
- Significantly larger patient pool in China and India; need for simple treatments

Market Drivers



- Launch and expansion of premium-priced therapeutics, including CPIs replacing inexpensive chemotherapies
- Increased incidence of HNSCC

¹ Globocan 2023.

² Global Data. 8MM includes US, 5EU (France, Germany, Italy, Spain, and the UK), Japan, and urban China

STS is a rare, heterogenous cancer


 Global incidence (16MM) of STS is ~128,000¹

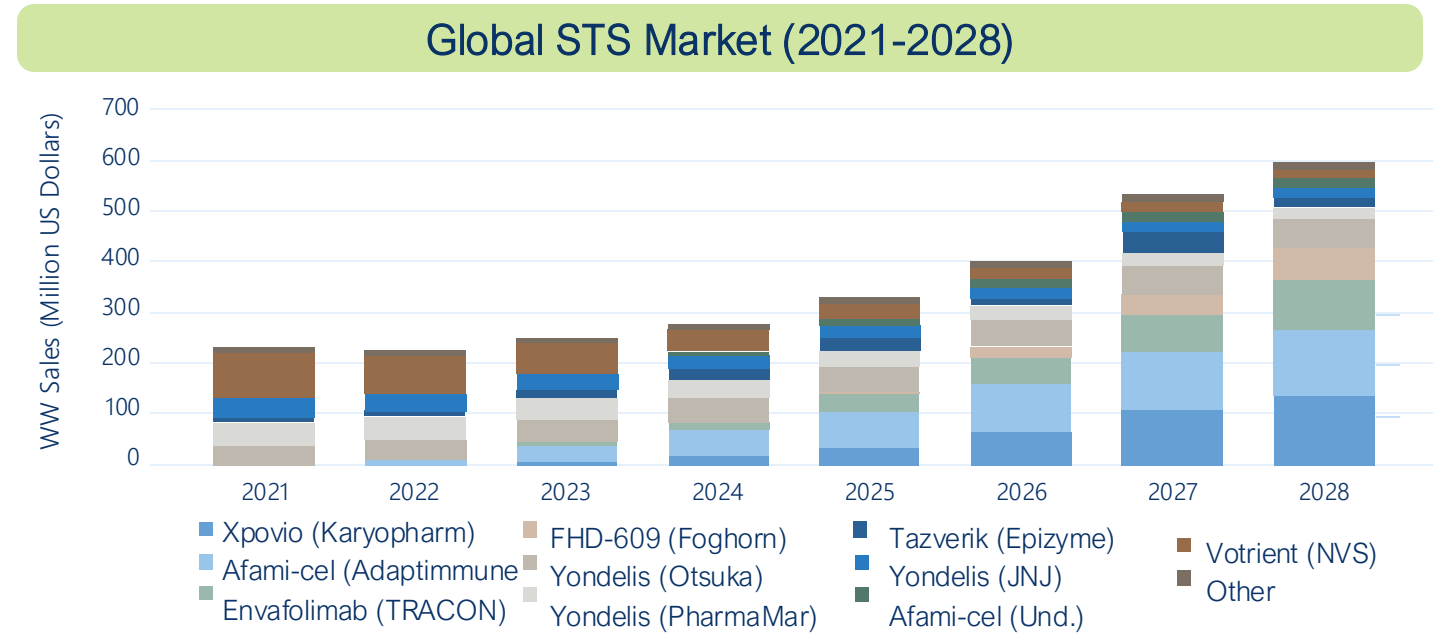
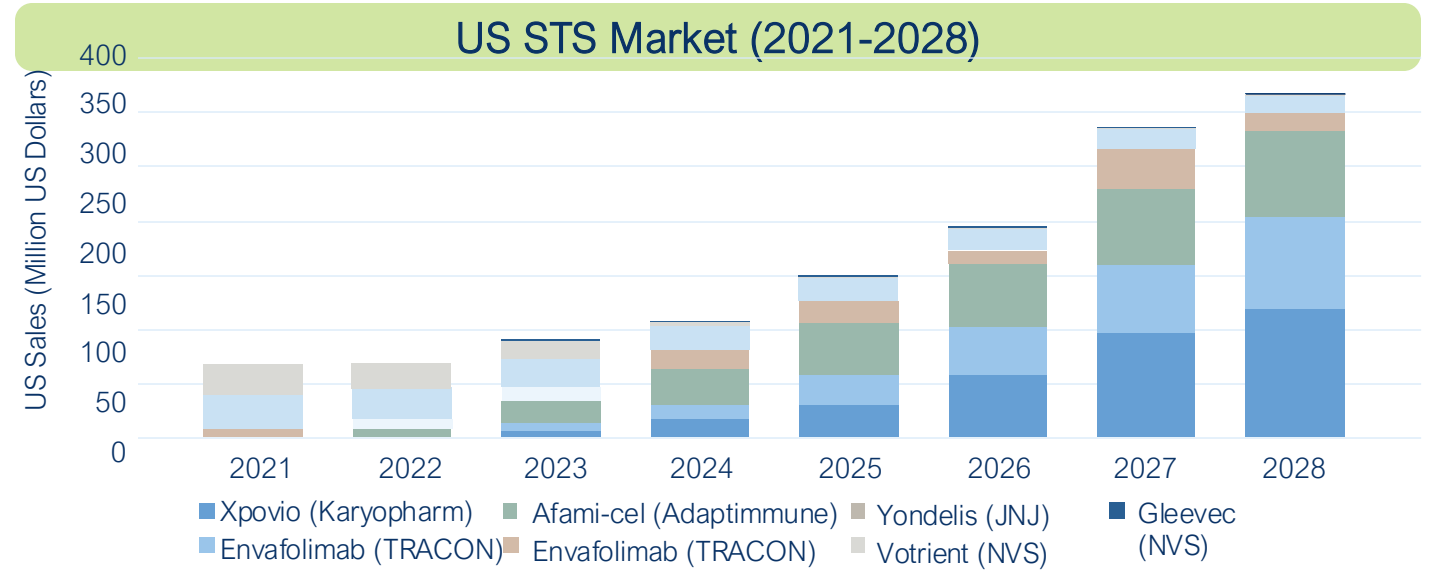
 STS SOC is surgery, radiation and chemotherapy

 Branded Market \$233M in 2022; US was \$83M (~35%)²

 Global market expected by 2028 to be ~\$596M

US market expected by 2028 to be ~\$372M (~62%)

 Market driven by subtype specific therapies, e.g. Votrient.
New approvals for targeted agents such as Xpovio, Envafohimab, and Afami-cel are expected to have significant market shares by 2028



¹GlobalData®, American Society, Cancer Australia, Cancer Research UK, Canadian Cancer Society
²Lumarity and EvaluatePharma

EBC-1013

Wound Healing

EBC-1013 for chronic and acute wounds and burns

6.5 million

US chronic wounds p.a.¹

14-29 million

globally p.a.²



Driven by ageing and increasing incidence of diabetes and obesity



Significant Unmet Need: 10% of chronic wounds do not heal



Current treatments - advanced wound dressings and medical devices, not pharmaceuticals



One product Regranex (Becaplermin) approved in USA



None approved in EU



Large failure rate; objective clinical endpoint = complete wound closure at 84 days

1.Hurlow et al, Defying the Recalcitrant Wound, Woundsource.com, Sponsored by ConvaTec.

2.Nussbaum et al, An Economic Evaluation of the Impact, Cost, and Medicare Policy Implications of Chronic Nonhealing Wounds. Value Health, 2018 Jan;21(1):27-32.

EBC-1013: Multi-faceted mode of action in wound healing



Cell signalling with multifactorial MOA affecting different stages of the wound healing process



Low competition (Pharmaceutical, not a device)



Potentially suitable for treating a wide range of chronic and acute traumatic wounds, including burns



Initial proof of concept of topical gel formulation from exploratory veterinary clinical case studies of difficult to treat wounds



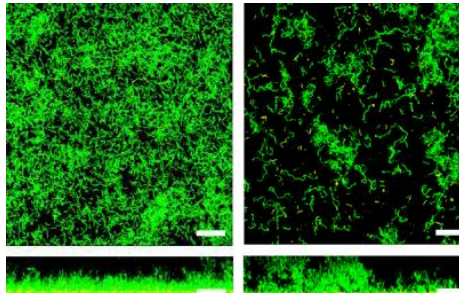
First-In-Human safety trial currently recruiting in patients with venous leg ulcers

EBC-1013: A novel small molecule for wound healing

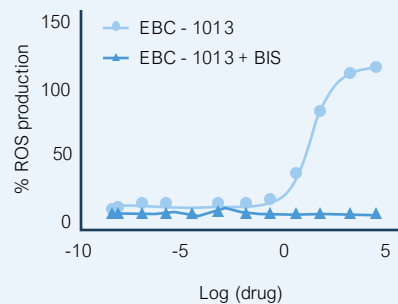
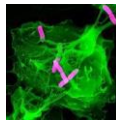
Antimicrobial

Disrupts the structure of established biofilms of multidrug resistant bacteria

Control EBC-1013

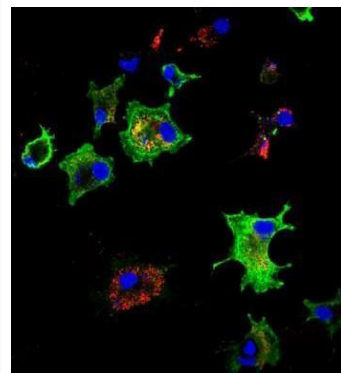


Induces respiratory burst by neutrophils



Drug induced debridement

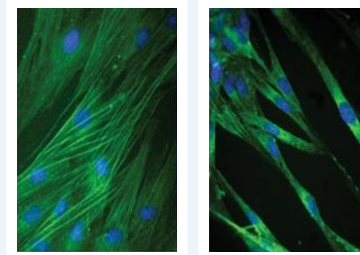
Patrolling monocytes differentiate into M1 & M2 macrophages



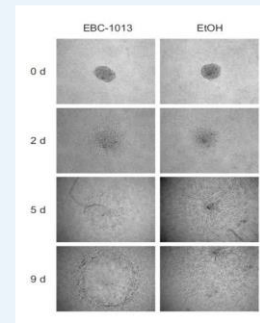
Proteolytic remodelling and deposition of extracellular matrix

Downregulates differentiation & formation of stress fibres by fibroblasts

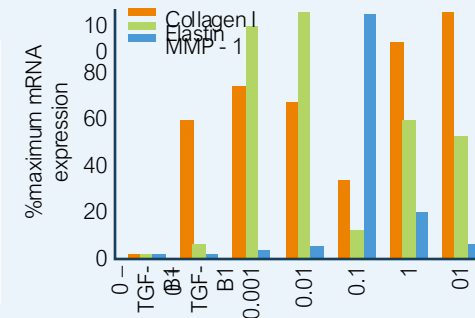
Control EBC-1013



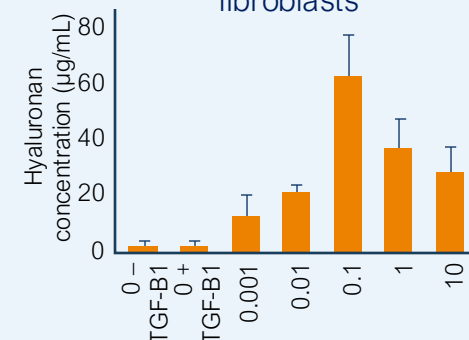
Degrades scar forming type I collagen (100 ng/ml)



Changes relative expression of key genes involved in ECM synthesis & remodelling



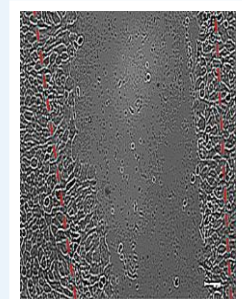
Stimulates production of hyaluronan by cultured fibroblasts



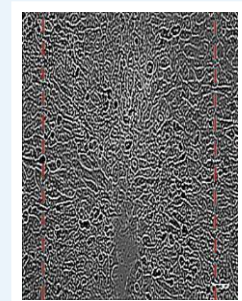
Wound closure

Stimulates migration of keratinocytes

Control



EBC-1013 (0.1 µg/ml)



EBC-1013: Reason to believe - veterinary case studies

Treatment with EBC-103 in gel

Canine 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



Treatment Day
(Infected wound 5 days after trauma)



5 days after treatment

Canine thermal burn (3 treatments, 7 days apart)



Treatment Day 1
(8 days after burn)



Day 14



Day 38



Day 73



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Group**

